Exhibit A

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

GEORGE BANNA,

Plaintiff,

v.

WALGREEN CO., *et al.*,

Defendants.

Consolidated for Pretrial and Discovery Purposes Under: No. 2020-L-004916

Judge Daniel Trevino

This Filing Applies to: All Actions

MASTER COMPLAINT

Plaintiffs, through undersigned counsel, bring this Master Long Form Complaint and Jury Demand ("Master Complaint") for personal injuries against the makers and retailers of Zantac and its generic, ranitidine, and allege as follows:

INTRODUCTION

1. Zantac is the branded name for ranitidine, a "blockbuster" drug that was sold as a safe and effective antacid. But ranitidine transforms over time and under particular conditions into high levels of N-Nitrosodimethylamine ("NDMA"), a carcinogen that is as potent as it is dangerous. After almost four decades and billions of dollars of sales, ranitidine consumption has caused scores of consumers to develop cancer. Plaintiffs bring this action for personal injuries resulting from Defendants' design, testing, marketing, labeling, packaging, handling, distribution, storage and sale of brand-name and generic ranitidine-containing products.

2. Until its 2020 recall by the FDA, ranitidine was a popular heartburn drug consumed by millions of people every day. Recent scientific studies, however, confirm what drug companies knew or should have known decades earlier: ingesting ranitidine exposes the consumer to unsafe and excessive amounts of NDMA.

3. NDMA is a well-known potent carcinogen. It was first discovered in the early 1900s as a byproduct of manufacturing rocket fuel. Today, its only use is to induce cancerous tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no medicinal purpose whatsoever.

4. NDMA is not akin to other compounds that have a salutary effect at low levels and a negative effect with greater exposure. There is no recommended daily dose of NDMA. The ideal level of exposure is zero. Nonetheless, the FDA previously set an allowable daily limit of NDMA of 96 nanograms (ng) to minimize the risks posed by this dangerous molecule. Yet a single pill of ranitidine can contain quantities of NDMA that are hundreds, if not thousands, of times higher than the allowable limit.

5. Those recent revelations by the scientific community have caused widespread recalls of ranitidine both domestically and internationally. In fact, after numerous voluntary recalls, on April 1, 2020, the FDA ordered the immediate withdrawal of all ranitidine-containing products sold in the United States, citing unacceptable levels of NDMA accumulation.

6. The high levels of NDMA observed in ranitidine-containing products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine into NDMA can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system.

7. Zantac wreaked such widespread harm in large part because GlaxoSmithKline—the inventor of ranitidine through its predecessors—succumbed to a temptation that is all too familiar to pharmaceutical innovators: maximizing the profits of an incredibly lucrative, government-conferred monopoly.

8. To encourage pharmaceutical companies to invest in research and development ("R&D"), the U.S. legal and regulatory system offers drug companies who invent "new chemical entities" two powerful inducements. First, innovators obtain patent protection for their pharmaceutical compounds. Second, approved new drugs enjoy FDA exclusivity, irrespective of whether the molecule is protected by one or more issued patents. Taken together, these policies assure that a pharmaceutical innovator will receive the exclusive right, for a limited period of time, to sell its drug to the American public.

9. As a result, branded drug manufacturers have a strong—and too often perverse—incentive to sell as much product as they can during their exclusivity window. That is why brand-name manufacturers spend billions of dollars per year in sales and marketing efforts to push incremental sales of a brand-name drug. Where every $1 in new sales can produce upwards of $0.90 in gross profit, staggering sales and marketing budgets are a very profitable investment. But while it makes sense for brand-name manufacturers to spend vast sums of money to develop and promote FDA approved drugs, they have no economic or regulatory incentive to uncover and investigate developing risks posed by their products.

10. That problem is especially acute for bestselling, blockbuster drugs. And Zantac is the brand that gave meaning to a blockbuster pharmaceutical product, becoming the first drug ever to generate over $1 billion in annual sales. Zantac's success catapulted Glaxo ahead of its previously larger rivals, fueling the market capitalization and corporate combinations that gave the company its current name: GlaxoSmithKline. It is little wonder Glaxo spared no expense to both get Zantac to market and to aggressively promote it to millions of consumers. Yet Glaxo did not part with a comparative pittance to investigate the obvious cancer risk posed by ranitidine. Turning a blind eye was far more profitable.

11. Generic ranitidine manufacturers share culpability for Plaintiffs' cancers, but for different and equally perverse reasons. To reduce the costs of medicine, Congress sought to ensure extensive competition once the exclusivity period for a brand-name drug expires. At that point, generic manufacturers may rapidly enter the market. They undergo a streamlined FDA approval process—through an Abbreviated New Drug Application ("ANDA")—without the need to replicate the expensive clinical trials to prove that the drug is safe and effective.

12. With a drug as popular as Zantac, generic competition is extensive and fierce. Without the benefit of a lawful monopoly or a strong brand name, generics are forced to compete on price, which dramatically undercuts the lucrative margins enjoyed by brand-name manufacturers. The FDA estimates that when a single generic enters the market, the average price of the drug falls by 39% compared to the branded-only monopoly. Once four generics enter the market, the average price falls by 79%. It takes only six generic competitors to reduce the price by more than 95%. But over the years, there were 75 FDA-approved ANDAs for generic ranitidine held by a multitude of generic manufacturers.

13. With razor thin margins and robust competition, a generic manufacturer faces its own economic temptation to cut corners, source ingredients as inexpensively as possible, and underinvest in quality control. And having already enjoyed a free ride on the brand's development of the drug, generic manufacturers also hope to free ride on some other company's investment in monitoring and analyzing emerging dangers posed by the products they are selling into the marketplace. But generic manufacturers are responsible for their own products. Thin margins and robust competition are not legally valid excuses for selling drugs that cause cancer.

14. Ultimately, the law holds every corporate entity in the supply chain of ranitidine responsible for the personal injuries caused by such an unsafe product. And the civil justice system

is the first, last, and only line of defense against the unchecked avarice that is a byproduct of a regulatory regime with the well-intentioned aim of bringing safe and effective medicines to market. Plaintiffs seek redress both as compensation for the horrific losses suffered in the past and to strongly deter future misconduct.

PARTIES

I. PLAINTIFFS

15. Plaintiffs in these individual actions are citizens and/or residents of the United States. Plaintiffs include those individuals who have suffered personal injuries in the form of cancer as a result of ingesting ranitidine. Plaintiffs also include spouses of those individuals who ingested ranitidine who have suffered injuries in the form of loss of consortium (hereinafter, "Plaintiff Spouses"). Plaintiffs also include the estates and/or representatives of individuals who are now deceased but suffered injuries in the form of cancer as a result of ingesting ranitidine.

16. During the time that Plaintiffs purchased and ingested ranitidine, they were not aware that ingesting ranitidine led to exposure to NDMA, or that ranitidine caused cancer.

17. As a result of Plaintiffs' cancers and subsequent treatment, Plaintiffs suffered and continue to suffer significant bodily injury, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

18. Based on prevailing scientific evidence, exposure to NDMA caused by consuming Defendants' ranitidine can cause cancer in humans.

19. Plaintiffs' cancers were caused by ingesting Zantac and/or generic Ranitidine.

II. DEFENDANTS

20. Defendants are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine that Plaintiffs ingested.

A. Brand-Name Manufacturers

Boehringer Ingelheim (BI)[1]

21. Boehringer Ingelheim Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer Ingelheim Pharmaceuticals, Inc., is a citizen of Delaware and Connecticut.

22. Boehringer Ingelheim International GmbH is a limited liability company formed and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim AM Rhein, Rheinland-Phalz, Germany. Boehringer Ingelheim International GmbH is a citizen of Germany.

23. Boehringer Ingelheim Promeco, S.A. de C.V. is a foreign corporation organized and existing under the laws of Mexico with its principal place of business located at Maiz No. 49, Barrio Xaltocan, Xochimilco, Ciudad de Mexico, 16090 Mexico. Boehringer Ingelheim Promeco, S.A. de C.V. is a citizen of Mexico.

24. Defendant Boehringer Ingelheim Corporation is a Nevada corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Defendant Boehringer Ingelheim Corporation is a citizen of Nevada and Connecticut.

25. Defendant Boehringer Ingelheim USA Corporation is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgebury, Connecticut 06877. Boehringer Ingelheim USA Corporation is a citizen of Delaware and Connecticut.

26. Collectively, these entities shall be referred to as "Boehringer Ingelheim" or "BI."

[1] Boehringer Ingelheim also manufactured generic ranitidine under ANDA 074662, as well as through its former subsidiary Ben Venue Laboratories Inc. d/b/a Bedford Laboratories (ANDA 074764). Ben Venue Laboratories Inc. is no longer in operation.

GlaxoSmithKline (GSK)

27. GlaxoSmithKline LLC is a Delaware limited liability company with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania, 19112. GlaxoSmithKline LLC's sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation with its principal place of business in that state. GlaxoSmithKline LLC is a citizen of Delaware.

28. GlaxoSmithKline Holdings (Americas) Inc. is a Delaware corporation with its principal place of business located at 1105 N. Market Street, Suite 622, Wilmington, Delaware 19801. GlaxoSmithKline Holdings (Americas) Inc. is a citizen of Delaware.

29. GlaxoSmithKline plc is a public limited company formed and existing under the laws of the United Kingdom, having a principal place of business at 980 Great West Road, Brentford Middlesex XO, TW8 9GS, United Kingdom. GlaxoSmithKline plc is a citizen of the United Kingdom.

30. GlaxoSmithKline LLC and GlaxoSmithKline Holdings (Americas) Inc. are subsidiaries of GlaxoSmithKline plc. Collectively, these entities shall be referred to as "GSK."

Pfizer

31. Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer is a citizen of Delaware and New York.

Sanofi

32. Sanofi-Aventis U.S. LLC is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC's sole member is Sanofi U.S. Services, Inc., a Delaware corporation with its principal

place of business in New Jersey. Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey.

33. Sanofi US Services Inc. is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services Inc. is a citizen of Delaware and New Jersey.

34. Chattem, Inc. (“Chattem”) is a Tennessee corporation with its principal place of business located at 1715 West 38th Street Chattanooga, Tennessee 37409. Chattem is a citizen of Tennessee. Chattem is a wholly owned subsidiary of Sanofi SA.

35. Chattem purchased ranitidine and repackaged and/or relabeled it under its own brand.

36. Defendant Patheon Manufacturing Services, LLC ("Patheon") is a limited liability company organized under the laws of Delaware. DPI Newco, LLC is the sole member of Patheon Manufacturing Services, LLC. Thermo Fisher (CN) Luxembourg Holding S.a.r.l. is the sole member of DPI Newco, LLC. Thermo CIDTEC, Inc. and TFS Life Holding, LLC are the two members of Thermo Fisher (CN) Luxembourg Holding S.a.r.l. Thermo CIDTEC, Inc. is incorporated in New York and also maintains its principal place of business in New York. TFS Life Holding, LLC has five members: (1) Thermo Fisher Scientific Life Technologies Investment UK I Limited, which is an English company; (2) Thermo Fisher Scientific Sweden Holdings, LLC; (3) Thermo Fisher Scientific Investments (Sweden) S.a.r.l.; (4) Thermo Fisher Scientific Life Investments U.S. Financing II, LLC; and (5) TFS Group Holding II, LLC. Thermo Fisher Scientific Sweden Holdings, LLC has two members, Thermo Fisher Scientific Investments (Sweden) S.a.r.l. and TFS Group Holding II, LLC. Thermo Fisher Scientific Investments (Sweden) S.a.r.l. has two members, CHK Holdings, Inc., a Delaware corporation with its principal

place of business in Massachusetts, and FSWH International Holdings, LLC. Fisher Scientific Worldwide Holdings, I C.V. is the sole member of FSWH International Holdings, LLC. Fisher Scientific Worldwide Holdings I C.V. has two members, Fisher Scientific Worldwide, Inc., a Delaware corporation with its principal place of business in Massachusetts, and FSIR Holdings (U.S.), Inc. also a Delaware corporation with its principal place of business in Massachusetts. TFS Group Holding II, LLC has two members, Thermo Fisher Scientific Life Investments C.V. and TFS Group Holding I, LLC. Thermo Fisher Scientific Life Investments C.V. has two members, Thermo Fisher Scientific Life Investments GP. LLC and Thermo Fisher Scientific Life Holdings II C.V., Thermo Fisher Scientific Life Holdings III C.V. is the sole member of Thermo Fisher Scientific Life Investments GP LLC. Thermo Fisher Scientific Life Holdings III C.V. has five members: (1) Thermo Fisher Scientific AL-1, LLC; (2) TFLP, LLC; (3) Thermo Fisher Scientific, Inc., a Delaware corporation with its principal place of business in Massachusetts; (4) Thermo BioAnalysis, LLC; and (5) Erie Scientific, LLC. TFLP, LLC is the sole member of Thermo Fisher Scientific AL-1, LLC. TFPL has five members: (1) Thermo Electron Corporation, a Delaware corporation with its principal place of business in Massachusetts; (2) Erie Scientific, LLC, whose sole member is Apogent Technologies, Inc., a Wisconsin corporation with its principal place of business in Massachusetts; (3) Apogent Technologies, Inc.; (4) Fisher Scientific Worldwide, Inc., a Delaware corporation with its principal place of business in Massachusetts; and (5) Fisher WWD Holding, LLC, whose sole member is Fisher Scientific Worldwide, Inc., a Delaware corporation with its principal place of business in Massachusetts. Thermo BioAnalysis, LLC has three members: (1) Thermo Fisher Scientific, Inc.; (2) Life Sciences International Limited, an English company; and (3) Life Sciences International, LLC, whose sole member is Helmet Securities Limited, an English company. TFS Group Holding I, LLC has twelve members: (1) Thermo Fisher

Scientific, Inc.; (2) Thermo Luxembourg Holding, LLC (Thermo Luxembourg Holding S.a.r.l.), whose sole member is Thermo Fisher Scientific Germany BV & Co. KG, which is owned by Thermo Fisher Scientific, Inc. and Thermo Fisher Scientific Germany B.V., a Dutch company; (3) Molecular Bioproducts, Inc., a California corporation with its principal place of business also in California; (4) Thermo Fisher Scientific Investments (Sweden) S.a.r.l., which has two members, CHK Holdings, Inc., a Delaware corporation with its principal place of business in Massachusetts, and FSWH International Holdings, LLC, whose sole member is Fisher Scientific Worldwide Holdings I, C.V., whose members are Fisher Scientific Worldwide, Inc., a Delaware corporation with its principal place of business in Massachusetts, and FSIR Holdings (U.S.), Inc., a Delaware corporation with its principal place of business in Massachusetts; (5) Fisher Scientific Worldwide Holdings I C.V.; (6) Thermo Fisher Scientific Life Investments U.S. Financing I, LLC, whose members are FSIR Holdings (U.S.), Inc. and FSWH International Holdings, LLC; (7) Fisher Scientific Worldwide, Inc.; (8) Fisher Clinical Services, Inc., a Pennsylvania corporation with its principal place of business also in Pennsylvania; (9) Liberty Lane Investment, LLC, whose sole member is FSIR Holdings (U.S.), Inc; (10) Fisher Scientific International, LLC, whose sole member is Thermo Fisher Scientific, Inc; (11) Thermo Fisher Scientific Life Investments U.S. Financing II, LLC, whose members are Perbio Science Sweden Holdings AB, a Swedish Company, and Thermo Fisher Scientific Life Investments II S.a.r.l., which is owned by Perbio Science AB, a Swedish company; and (12) Erie LP Holding, LLC, whose sole member is Erie UK Holding Company, a Delaware corporation with its principal place of business in Massachusetts. Consequently, Patheon Manufacturing Services, LLC is a citizen of a number of different states and countries, including Delaware, New York, California, Massachusetts, Wisconsin and Pennsylvania. Further, Patheon was, at times, engaged in the manufacture, distribution, labeling,

packaging, handling, storage, transport and/or selling of OTC Zantac on behalf of Defendants GSK, Pfizer, BI and Sanofi from 1995 until it was withdrawn from the market due to unsafe levels of NDMA found in products.

37. Patheon Manufacturing Services LLC packaged and manufactured the finished Zantac product for Sanofi. Collectively, these entities shall be referred to as "Sanofi."

38. The above-described Defendants shall be referred to collectively as the "Brand-Name Manufacturers."

39. At all relevant times, the Brand-Name Manufacturers have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Zantac within Illinois.

B. Generic Manufacturers

Ajanta

40. Ajanta Pharma USA Inc. is a New Jersey corporation with its principal place of business located at 440 U.S. Highway 22, Ste. 150, Bridgewater, NJ 08807. Ajanta Pharma USA Inc. is a citizen of New Jersey.

41. Ajanta Pharma USA Inc. is Ajanta Pharma Ltd.'s appointed agent in the United States for the very purpose of lawfully selling and distributing drugs including ranitidine-containing products. Ajanta Pharma USA Inc. as a regulatory agent also fulfills a regulatory compliance role for Ajanta Pharma Ltd. by regularly filing materials the FDA requires ANDA holders to provide to maintain their right to manufacture drugs.

42. Ajanta Pharma Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at 9 Ajanta House Charkop, Kandivili (West), Mumbai, Maharashtra, India. Defendant Ajanta Pharma Ltd. is a citizen of India.

43. Ajanta Pharma Ltd. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. It also applied to the US FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States. Further, Ajanta Pharma, Ltd. registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

44. Ajanta Pharma USA Inc. is a subsidiary of Ajanta Pharma Ltd. Collectively, these entities shall be referred to as "Ajanta."

45. Ajanta manufactured and/or purchased ranitidine and repackaged and/or relabeled it under Ajanta's own brand.

Amneal

46. Amneal Pharmaceuticals LLC is a Delaware limited liability company with its principal place of business located at 400 Crossing Blvd., Bridgewater, New Jersey 08807. The sole member of Amneal Pharmaceuticals LLC is non-party Amneal Pharmaceuticals, Inc., a Delaware corporation with its principal place of business in New Jersey. Amneal Pharmaceuticals LLC is a citizen of Delaware and New Jersey.

47. Amneal Pharmaceuticals LLC registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

48. Amneal Pharmaceuticals of New York, LLC is a Delaware limited liability company with its principal place of business located at 50 Horseblock Road, Brookhaven, New York 11719. The membership interest of Amneal Pharmaceuticals of New York, LLC is owned by non-party Amneal Pharmaceuticals, Inc., a Delaware corporation with its principal place of business located in New Jersey, through an intervening limited liability company. Amneal Pharmaceuticals of New York, LLC is a citizen of Delaware and New Jersey.

49. Amneal Pharmaceuticals of New York, LLC applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Amneal Pharmaceuticals of New York, LLC applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States. Amneal Pharmaceuticals of New York, LLC registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

50. Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC are subsidiaries of non-party Amneal Pharmaceuticals, Inc. Collectively, these entities shall be referred to as "Amneal."

51. Amneal manufactured and/or purchased ranitidine and repackaged and/or relabeled it under its own brand.

Apotex

52. Apotex Corporation is a Delaware corporation with its principal place of business located at 2400 N. Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex Corporation is a citizen of Delaware and Florida.

53. Apotex Corporation applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States. Further, Apotex Corporation is Apotex Inc.'s appointed agent in the United States for the very purpose of lawfully selling and distributing drugs including ranitidine-containing products. Apotex Corporation as a regulatory agent also fulfills a regulatory compliance role for Apotex Inc. by regularly filing materials the FDA requires ANDA holders to provide to maintain their right to manufacture drugs.

54. Apotex Inc. is a corporation organized and existing under the laws of Canada with its principal place of business located at 150 Signet Drive, Toronto, Ontario, M9L 1T9 Canada. Apotex Inc. is a citizen of Canada.

55. Apotex Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Further, Apotex Inc. registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

56. Apotex Corporation is a subsidiary of Apotex Inc. Collectively, these entities shall be referred to as "Apotex."

57. Apotex manufactured and/or purchased ranitidine and repackaged and/or relabeled it under Apotex's own brand.

Dr. Reddy's

58. Dr. Reddy's Laboratories, Inc. is a New Jersey corporation with its principal place of business located at 107 College Rd. E, Princeton, New Jersey 08540. Dr. Reddy's Laboratories, Inc. is a citizen of New Jersey.

59. Dr. Reddy's Laboratories, Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Dr. Reddy's Laboratories, Inc. also applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States.

60. Dr. Reddy's Laboratories, Inc. is also the appointed agent in the United States for the very purpose of lawfully selling and distributing drugs including ranitidine-containing products manufactured by Dr. Reddy's Laboratories, Ltd. Dr. Reddy's Laboratories, Inc. as a regulatory agent also fulfills a regulatory compliance role for other Dr. Reddy's entities by regularly filing materials the FDA requires ANDA holders to provide to maintain their right to manufacture drugs.

61. Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at 8-2-337, Road No. 3, Banjara Hills, Hyderabad Telangana 500 034, India. Dr. Reddy's Laboratories, Ltd. is a citizen of India.

62. Dr. Reddy's Laboratories, Ltd. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Dr. Reddy's Laboratories, Ltd. also applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States. Dr. Reddy's Laboratories, Ltd. further registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

63. Dr. Reddy's Laboratories Louisiana LLC is a limited liability company with its principal place of business located at 107 College Road East, Princeton, NJ 08540. The LLC has three registered officers, each of whom are citizens of New Jersey.

64. Dr. Reddy's Laboratories Louisiana LLC registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

65. Dr. Reddy's Laboratories SA is a corporation organized and existing under the laws of Switzerland with its principal place of business located at Elisabethenanlage, 11, Basel, 4051 Switzerland. Dr. Reddy's Laboratories SA is a citizen of Switzerland.

66. Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories Louisiana LLC are subsidiaries of Dr. Reddy's Laboratories SA. Collectively, these entities shall be referred to as "Dr. Reddy's."

67. Dr. Reddy's manufactured and/or purchased ranitidine and repackaged and/or relabeled it under its own brand.

Glenmark

68. Glenmark Pharmaceuticals, Inc., USA (f/k/a Glenmark Generics, Inc. USA) is a Delaware corporation with its principal place of business located at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark Pharmaceuticals, Inc., USA is a citizen of Delaware and New Jersey.

69. Glenmark Pharmaceuticals, Inc., USA applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Glenmark Pharmaceuticals, Inc., USA also applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States.

70. Glenmark Pharmaceuticals, Inc., USA is also Glenmark Pharmaceuticals Ltd.'s appointed agent in the United States for the very purpose of lawfully selling and distributing drugs including ranitidine-containing products. Glenmark Pharmaceuticals, Inc., USA as a regulatory agent also fulfills a regulatory compliance role for Glenmark Pharmaceuticals Ltd. by regularly filing materials the FDA requires ANDA holders to provide to maintain their right to manufacture drugs.

71. Glenmark Pharmaceuticals Ltd. (f/k/a Glenmark Generics Ltd.) is a corporation organized and existing under the laws of India with its principal place of business located at Glenmark House, B.D. Sawant Marg., Chakala, Western Express Highway, Andheri (E), Mumbai 400 099, India. Glenmark Pharmaceuticals Ltd. is a citizen of India.

72. Glenmark Pharmaceuticals Ltd. registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

73. Glenmark Pharmaceuticals, Inc., USA is a subsidiary of Glenmark Pharmaceuticals Ltd. Collectively, these entities shall be referred to as "Glenmark."

74. Glenmark manufactured and/or purchased ranitidine and repackaged and/or relabeled it under its own brand.

Novitium

75. Novitium Pharma LLC ("Novitium") is a Delaware limited liability company with its principal place of business located at 70 Lake Drive, East Windsor, New Jersey 08520. Upon information and belief, the member(s) of Novitium and the company itself are citizens of New Jersey.

76. Novitium applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Novitium also applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States.

77. Novitium manufactured and/or purchased ranitidine and repackaged and/or relabeled it under Novitium's own brand.

Perrigo

78. L. Perrigo Co. is a Michigan corporation with its principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010. L. Perrigo Co. is a citizen of Michigan.

79. L. Perrigo Co. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. L. Perrigo Co. also applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States. L. Perrigo Co. further registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

80. Perrigo Company is a Michigan corporation with its principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo Company is a citizen of Michigan.

81. Perrigo Research & Development Company is a Michigan corporation with its principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo Research & Development Company is a citizen of Michigan.

82. Perrigo Research & Development Company applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

83. L. Perrigo Co., Perrigo Company, and Perrigo Research & Development Company are subsidiaries of non-party Perrigo Company, plc., a corporation organized and existing under the laws of Ireland with its principal place of business in Ireland. Collectively, these entities shall be referred to as "Perrigo."

84. Perrigo manufactured and/or purchased ranitidine and repackaged and/or relabeled it under Perrigo's own brand.

Sandoz

85. Sandoz Inc. ("Sandoz") is a Colorado corporation with its principal place of business located at 100 College Road West, Princeton, New Jersey 08540. Sandoz is a citizen of Colorado and New Jersey.

86. Sandoz applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Sandoz applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States.

87. Sandoz manufactured and/or purchased ranitidine and repackaged and/or relabeled it under its own brand.

Strides

88. Strides Pharma, Inc. ("Strides") is a New Jersey corporation with its principal place of business located at 2 Tower Center Blvd., Suite 1102, East Brunswick, New Jersey 08816. Strides is a citizen of New Jersey.

89. Strides registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

90. Strides manufactured and/or purchased ranitidine and repackaged and/or relabeled it under Strides' own brand.

Teva

91. Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business located at 1877 Kawai Rd., Lincolnton, North Carolina 28092. The membership interest of Actavis Mid Atlantic LLC is owned by Teva Pharmaceuticals U.S.A., Inc., either directly or through an intervening limited liability company. Teva Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business in Pennsylvania. Actavis Mid Atlantic LLC is a citizen of Delaware and Pennsylvania.

92. Actavis Mid Atlantic LLC applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

93. Teva Pharmaceuticals U.S.A., Inc. is a Delaware corporation with its principal place of business located at 1090 Horsham Road North Wales, Pennsylvania 19454. Teva Pharmaceuticals U.S.A., Inc. is a citizen of Delaware and Pennsylvania.

94. Teva Pharmaceuticals U.S.A., Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

95. Ivax Pharmaceuticals LLC was a Florida limited liability company with its principal place of business located in Miami, Florida. Teva Pharmaceuticals acquired Ivax Pharmaceuticals in 2005.

96. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business located at 400 Interpace Parkway, Bldg. A., Parsippany, New Jersey, 07054. Watson Laboratories, Inc. is a citizen of Nevada and New Jersey.

97. Watson Laboratories, Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

98. Actavis Mid Atlantic LLC, Teva Pharmaceuticals U.S.A., Inc., and Watson Laboratories, Inc. are subsidiaries of non-party Teva Pharmaceutical Industries Ltd., a corporation organized and existing under the laws of Israel with its principal place of business located in Israel. Collectively, these entities shall be referred to as "Teva."

Sun Pharmaceutical

99. Ranbaxy Inc. is a Texas corporation with its principal place of business located at 2 Independence Way, Princeton, New Jersey 08540. Ranbaxy Inc. is a citizen of Texas and New Jersey.

100. Ranbaxy Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

101. Sun Pharmaceutical Industries, Inc., f/k/a Ranbaxy Pharmaceuticals Inc., is a Delaware corporation with is principal place of business located at 2 Independence Way, Princeton, New Jersey 08540. Sun Pharmaceutical Industries, Inc. is a citizen of Delaware and New Jersey.

102. Sun Pharmaceutical Industries, Inc. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

103. Sun Pharmaceutical Industries Ltd. is corporation organized and existing under the laws of India with its principal place of business located at Western Express Highway Sun House, CTS No 201 B/1 Goregaon East, Mumbai, 400 063 India. Sun Pharmaceutical Industries Ltd. is a citizen of India.

104. Sun Pharmaceutical Industries Ltd. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein.

105. Ranbaxy Inc., Sun Pharmaceutical Industries, Inc. (f/k/a Ranbaxy Pharmaceuticals Inc.), and Sun Pharmaceutical Industries Ltd. are subsidiaries of non-party Taro Pharmaceutical Industries Ltd., a corporation organized and existing under the laws of Israel with its principal place of business located in Israel. Collectively, these entities shall be referred to as "Sun Pharmaceutical."

Wockhardt

106. Wockhardt USA LLC is a Delaware limited liability company with its principal place of business located at 20 Waterview Blvd., Parsippany, New Jersey 07054. Upon information and belief, the sole member of Wockhardt USA LLC is Wockhardt USA, Inc., a Delaware corporation with its principal place of business in New Jersey. Wockhardt USA LLC is a citizen of Delaware and New Jersey.

107. Wockhardt USA LLC applied to the FDA for the power and privilege of listing and labeling ranitidine-containing products for sale in all states and territories within the United States.

108. Wockhardt USA, Inc. is a Delaware corporation with its principal place of business located at 135 Route 202/206, Bedminster, New Jersey 07921. Wockhardt USA, Inc. is a citizen of Delaware and New Jersey.

109. Wockhardt USA, Inc. is Wockhardt Ltd.'s appointed agent in the United States for the very purpose of lawfully selling and distributing drugs including ranitidine-containing

products. Wockhardt USA, Inc. as a regulatory agent also fulfills a regulatory compliance role for Wockhardt Ltd. by regularly filing materials the FDA requires ANDA holders to provide to maintain their right to manufacture drugs.

110. Wockhardt Ltd. is a corporation organized and existing under the laws of India with its principal place of business located at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India. Wockhardt Ltd. is a citizen of India.

111. Wockhardt Ltd. applied to the FDA for the right to manufacture and sell a generic form of ranitidine and subsequently received that approval as discussed herein. Wockhardt Ltd. also registered an establishment with the FDA, allowing it to manufacture, repack, or relabel drug products within the United States.

112. Wockhardt Ltd. wrote to the FDA in 2004, informing the FDA that its president maintained an office, located in Rockville, Maryland and had local phone and fax numbers. The letter further confirms that the president of the company is responsible for liaising with the FDA for all regulatory matters, including ANDAs, DMFs, NDC listings, among other things.

113. Wockhardt USA LLC and Wockhardt USA, Inc. are subsidiaries of Wockhardt Ltd., a corporation organized and existing under the laws of India with its principal place of business in India. Collectively, these entities shall be referred to as "Wockhardt."

114. Wockhardt manufactured and/or purchased ranitidine and repackaged and/or relabeled it under Defendant's own brand.

115. The above-described Defendants shall be referred to collectively as the "Generic Manufacturers."

116. At all relevant times, the Generic Manufacturers have conducted business and derived substantial revenue from their design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of Zantac within Illinois.

C. Retailers

Walgreens

117. Walgreen Co. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreen Co. is a citizen of Delaware and Illinois.

118. Duane Reade, Inc. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Duane Reade, Inc. is a citizen of Delaware and Illinois.

119. Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business located at 108 Wilmot Road, Deerfield, Illinois 60015. Walgreens Boots Alliance, Inc. is a citizen of Delaware and Illinois.

120. Walgreens Boots Alliance, Inc. purchased ranitidine and repackaged and/or relabeled it under its own brand.

121. Walgreen Co. and Duane Reade, Inc. are subsidiaries of Walgreens Boots Alliance, Inc. Collectively, these entities shall be referred to as "Walgreens."

Walmart

122. Walmart Inc. f/k/a Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business located at 702 SW 8th Street, Bentonville, Arkansas 72716. Walmart Inc. is a citizen of Delaware and Arkansas.

123. Sam's West Inc. is an Arkansas corporation with its principal place of business located at 702 SW 8th Street, Bentonville, Arkansas 72716. Walmart Inc. is a citizen of Arkansas.

124. Sam's West, Inc. is a subsidiary of Walmart, Inc. Collectively, these entities shall be referred to as "Walmart."

125. The above-described Defendants shall be referred to collectively as the "Retailers."

126. At all relevant times, the Retailers have conducted business and derived substantial revenue from marketing, handling, distributing, storing, and selling ranitidine-containing products within each of the States and Territories of the United States, including Illinois.

JURISDICTION & VENUE

127. This Court has subject matter jurisdiction pursuant to 735 ILCS 5/2-209(b)(3)–(4).

128. This Court has personal jurisdiction over Defendants insofar as Defendants are authorized and licensed to conduct business in Illinois, maintain and carry on systematic and continuous contacts in Illinois, and regularly transacts business within Illinois, including with Plaintiffs.

129. Additionally, the Defendants caused injury and death by acts and omissions in Illinois and caused injury and death in Illinois by acts and omissions outside Illinois while regularly doing and soliciting business, engaging in a persistent course of conduct, and receiving financial benefit and profits from goods used or consumed in Illinois.

130. At all relevant times, Defendants were present and doing business in Illinois, and should have expected that their acts would have consequences within the state of Illinois.

131. During the relevant time period, many Plaintiffs took Zantac or generic ranitidine in Illinois, as stated more specifically in each Plaintiff's separate complaint.

132. Venue is proper because a substantial part of the events, actions, or omissions giving rise to Plaintiffs' causes of action occurred in Illinois. 735 ILCS 5/2-101. Venue is also proper pursuant to Illinois Supreme Court Order consolidating all cases involving ranitidine claims

and transferring them for pretrial proceedings only in Cook County. Order, *Banna v. Walgreens Co., et al.*, Ill. Sup. Ct. No. 129094 (November 23, 2022).

FACTUAL ALLEGATIONS

I. THE CREATION OF RANITIDINE-CONTAINING PRODUCTS AND THEIR INTRODUCTION TO THE MARKET

133. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine under the brand name Zantac or a generic equivalent by either prescription or over the counter ("OTC").

A. GSK Develops Zantac Through a Flurry of Aggressive Marketing Maneuvers

134. Ranitidine belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Axid).

135. GSK-predecessor Smith, Kline & French discovered and developed Tagamet, the first H2 blocker and the prototypical histamine H2 receptor antagonist from which the later members of the class were developed.

136. GSK[2] developed Zantac specifically in response to the success of cimetidine. Recognizing the extraordinary potential of having its own H2 blocker in the burgeoning anti-ulcer market, GSK was all too willing to ensure its drug succeeded at all costs.

[2] GSK, as it's known today, was created through a series of mergers and acquisitions: In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In 1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000, Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

137. Allen & Hanburys Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule.

138. In 1983, the FDA granted approval to Glaxo to sell Zantac, pursuant to the New Drug Application ("NDA") No. 18-703, and it quickly became GSK's most successful product—a "blockbuster." Indeed, Zantac became the first prescription drug in history to reach $1 billion in sales.

139. To accomplish this feat, GSK entered into a joint promotion agreement with Hoffmann-LaRoche, Inc. More salespersons drove more sales and blockbuster profits for GSK.

140. In June of 1986, the FDA approved Zantac for maintenance therapy of duodenal ulcers and for treatment of patients with gastroesophageal reflux disease (GERD).

141. In December 1993, GSK (through Glaxo Wellcome plc) entered into a partnership agreement with Pfizer-predecessor company Warner-Lambert Co. to develop and market an OTC version of Zantac. In 1995, the FDA approved OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved OTC Zantac 75 mg effervescent tablets through NDA 20-745.

142. All OTC brand named Zantac formulations were submitted and approved as new NDAs under § 505(b) of the FDCA:

a. NDA 20-520 was approved by the FDA on December 19, 1995, and was issued to Glaxo Wellcome, Inc.;

b. NDA 20-745 was approved by the FDA on February 26, 1998, and was issued to Glaxo Wellcome, Inc.; and

c. NDA 21-698 was approved by the FDA on September 31, 2004, and was issued to Pfizer.

143. Subsequent formulations and variations of brand name and generic Zantac were approved by the FDA as ANDAs or sNDAs under the heading of the above-listed NDAs.

144. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their partnership. As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada but was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK retained rights to sell OTC Zantac outside of the United States and Canada, and retained control over the Zantac trademark internationally.

145. In 2000, Pfizer acquired Warner-Lambert Co. Pfizer controlled the Zantac OTC NDAs until December 2006.

146. In October 2000, GSK sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GSK divested all domestic Zantac OTC assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription ranitidine-containing product in the United States.

147. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150 mg. The FDA approved NDA 21-698 on August 31, 2004.

148. During the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

149. In 2006, pursuant to a Stock and Asset Purchase Agreement, Pfizer sold and divested its entire consumer health division (including employees and documents) to Johnson &

Johnson ("J&J"). Because of antitrust issues, however, Zantac was transferred to Boehringer Ingelheim.

150. Pfizer, through a divestiture agreement, transferred all assets pertaining to its Zantac OTC line of products, including the rights to sell and market all formulations of OTC Zantac in the United States and Canada, as well as all intellectual property, R&D, and customer and supply contracts to Boehringer Ingelheim. As part of that deal, Boehringer Ingelheim obtained control and responsibility over all Zantac OTC NDAs.

151. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac. According to its recent annual report, GSK claims to have "discontinued making and selling prescription Zantac tablets in 2017 . . . in the U.S."[3]

152. Boehringer Ingelheim owned and controlled the NDA for OTC Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period.[4]

153. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to an asset swap agreement. As part of that deal, Sanofi obtained control and responsibility over Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. As part of this agreement, Boehringer Ingelheim and Sanofi entered into a manufacturing agreement wherein Boehringer continued to manufacture OTC Zantac for Sanofi.

[3] GlaxoSmithKline, plc, *Annual Report* 37 (2019), https://www.gsk.com/media/5894/annual-report.pdf.

[4] Boehringer Ingelheim also owned and controlled ANDA 074662.

154. Sanofi has controlled the OTC Zantac NDAs and marketed, sold, and distributed Zantac in the United States from January 2017 until 2019 when it issued a global recall and ceased marketing, selling, and distributing OTC Zantac. In addition, Sanofi has marketed, sold, and distributed ranitidine globally since 1983.

155. Throughout the time that Sanofi controlled the OTC Zantac NDAs, Boehringer Ingelheim Promeco, S.A. de C.V. and Patheon Manufacturing Services LLC manufactured the finished drug product.

156. Sanofi voluntarily recalled all brand-name OTC Zantac and ranitidine on October 18, 2019.

157. Pfizer and Boehringer Ingelheim have made demands for indemnification per the Stock and Asset Purchase Agreement against J&J for legal claims related to OTC Zantac products.

158. Sanofi has made a demand for indemnification against J&J pursuant to a 2016 Asset Purchase Agreement between J&J and Sanofi.

159. The times during which each Brand-Name Manufacturer manufactured and/or sold branded Zantac are alleged below:

Manufacturer/ Repackager	Product	Prescription or Over the Counter	Sale Start Date Year	Sale End Date Year
GlaxoSmithKline	Pills, Syrup, and Injection Pills	Prescription OTC	1983 1995	2019 2004
Pfizer	Pills	OTC	1998	2006
Boehringer Ingelheim	Pills	OTC	2007	2019
Sanofi	Pills	OTC	2017	2019

B. Patents Expire, Allowing Generics to Enter the Market

160. In 1997, GSK's patent on the original prescription Zantac product expired, allowing generic manufacturers to sell prescription ranitidine.

161. When GSK and Pfizer's patent on the original OTC Zantac product expired, generic manufacturers were allowed to sell OTC ranitidine.

162. The FDA approved numerous generic manufacturers for the sale of prescription and OTC ranitidine through the ANDA process.

163. "An abbreviated new drug application (ANDA) contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references."[5]

164. Generic drugs must be comparable to the branded drug in dosage form, strength, route of administration, quality, performance characteristics, and intended use.[6]

165. ANDA applicants generally do not need to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product performs in the same manner as the innovator drug, known as "bioequivalence."

166. Once a manufacturer's ANDA is approved, that manufacturer is subject to post-market obligations. These obligations include submitting annual reports to the FDA, tracking and reporting adverse events, and tracking and reporting relevant medical literature, among other things.

[5] *Abbreviated New Drug Application (ANDA)*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda (last visited Dec. 19, 2022).
[6] *Id.*

167. These ANDA approvals allowed the Generic Defendants to sell their ranitidine products throughout the country. And the Generic Defendants did so.

168. All Defendants who have the power of labeling and listing drugs within the United States must obtain a National Drug Code ("NDC"). All NDC holders are required to register all drugs and list them with the FDA.

169. All Defendants who have registered establishments with the FDA must provide "[c]omplete, accurate and up-to-date establishment registration and drug listing information [which] is essential to promote patient safety. FDA relies on establishment registration and drug listing information for several key programs, including:

- Drug establishment inspections
- Post market surveillance
- Counterterrorism
- Recalls
- Drug quality reports
- Adverse event reports
- Monitoring of drug shortages and availability
- Supply chain security
- Drug import and export
- Identification of products that are marketed without an approved application"[7]

[7] *Electronic Drug Registration and Listing System (eDRLS)*, U.S. Food & Drug Admin. (Dec. 18, 2020), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls.

170. In registering with the FDA to manufacture, label, distribute, and sell ranitidine-containing products within all U.S. states and territories, all defendants holding an ANDA or NDC Code, or which registered an establishment had an obligation to comply with federal law.

171. Plaintiffs assert claims against these Generic Defendants as to the time during which each sold ranitidine to Plaintiffs.

172. Based upon the information released by Defendants, the following generic manufacturers manufactured Ranitidine-Containing Products during the following date ranges. Upon information and belief, each entity began researching Ranitidine-Containing Products at least one year prior to the date they commenced selling the product and therefore knew or should have known of all risks associated with Ranitidine-Containing Products discussed herein from that date onward:

Manufacturer/ Repackager (by Corporate Family)	Product	Rx or OTC	Sale Start Date Year	Sale End Date Year
Ajanta	Pills	Rx	2018	2020
Amneal	Pills and Syrup	Rx and OTC	2009	2019
Apotex	Pills and Syrup	Rx and OTC	1997	2019
Dr. Reddy's	Pills	Rx OTC	2001 2008	2019 2019
Glenmark	Pills	Rx	2009	2019
Novitium	Pills	Rx	2018	2019
Perrigo	Pills	OTC	2003	2019
Sandoz	Pills	Rx	1997	2019
Strides	Pills	Rx OTC	2016 2012	2020 2018
Teva	Pills and Syrup	Rx OTC	1998 2000	2016 2008
Sun Pharmaceutical	Pills	Rx and OTC	2000	2017
Wockhardt	Pills and Syrup	Rx	2003	2015

		OTC	2010	2014

173. Despite generic entry, Brand-Name Manufacturers continued to sell prescription and OTC Zantac. Although sales of Zantac declined as a result of generic competition, ranitidine sales remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablets in the United States, with sales of OTC Zantac 150 totaling $128.9 million—a 3.1% increase from the previous year.

II. NDMA IS A CARCINOGEN WHOSE DANGEROUS PROPERTIES ARE WELL ESTABLISHED

174. According to the Environmental Protection Agency ("EPA"), "NDMA is a semivolatile organic chemical that forms in both industrial and natural processes."[8] It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[9] NDMA is no longer produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

[8] U.S. Environmental Protection Agency, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[9] Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, The Globe & Mail (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve's Water*, The Globe & Mail (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA Adducts in Humans After Exposure to Methylating Agents*, 405 Mut. Res. 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

175. Both the EPA and the International Agency for Research on Cancer ("IARC") classify NDMA as a probable human carcinogen.[10]

176. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[11]

177. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[12] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[13]

178. The FDA considers NDMA a carcinogenic impurity and chemical that "could cause cancer" in humans.[14] The FDA recognizes that NDMA is "known to be toxic."[15]

179. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[16] NDMA

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[10] *See* EPA Technical Fact Sheet, *supra* note 8; Int'l Agency for Research on Cancer (IARC), *Summaries & Evaluations, N-NITROSODIMETHYLAMINE*, World Health Org. Internationally Peer Reviewed Chemical Safety Info. (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html.

[11] *See* EPA Technical Fact Sheet, *supra* note 8.

[12] *Id.* at 3.

[13] *Id.*

[14] FDA Statement, Janet Woodcock, Director – Ctr. for Drug Evaluation & Research, *Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[15] Amneal_prod 1 _ 0000002938.

[16] World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

belongs to the so-called "cohort of concern" which is a group of highly potent mutagenic carcinogens that have been classified as probable human carcinogens.[17]

180. The EMA has referred to NDMA as "highly carcinogenic." It recommended that "primary attention with respect to risk for patients should be on these highly carcinogenic N-nitrosamines" (including NDMA), and categorized NDMA as "of highest concern with respect to mutagenic and carcinogenic potential."[18]

181. In 1989, the Agency for Toxic Substances and Disease Registry (ATSDR) stated that it is "reasonable to expect that exposure to NDMA by eating, drinking or breathing could cause cancer in humans" and that the "carcinogenicity of orally-administered NDMA has been demonstrated unequivocally in acute, intermediate and chronic durations studies" in animals and "it is important to recognize that this evidence also indicates that oral exposures of acute and intermediate duration are sufficient to induce cancer." Moreover, "hepatoxicity has been demonstrated in all animal species that have been tested and has been observed in humans who were exposed to NDMA by ingestion or inhalation."[19]

182. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

183. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—Valsartan, Losartan, and

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[17] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, M7(R1), March 2017, https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf.

[18] Nitrosamines EMEA-H-A5(3)-1490 - Assessment Report (europa.eu) (June 25, 2020), https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf.

[19] ATSDR Toxicological Profile For N-Nitrosodimethylamine (December 1989), http://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

Irbesartan—because the medications contained nitrosamine impurities that do not meet the FDA's safety standards. Some of the manufacturers of those contaminated medications also are parties to this case, including Teva.

184. This continued in 2020 when the FDA required recalls of numerous generic manufacturers' metformin, including metformin made by Sun Pharmaceuticals and Teva.[20]

185. NDMA is a genotoxin which interacts with DNA and may subsequently induce mutations. Genotoxins are not considered to have a safe threshold or dose due to their ability to alter DNA.

186. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 ng is considered unacceptable.[21]

187. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung.

188. In other long-term animal studies in mice and rats utilizing different routes of exposures—inhalation, subcutaneous injection, and intraperitoneal (abdomen injection)—cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

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[20] *FDA Updates and Press Announcements on NDMA in Metformin*, U.S. Food & Drug Admin. (Jan. 6, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin.

[21] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Feb. 28, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

189. Numerous in vitro studies confirm that NDMA is a mutagen—causing genetic mutations in human and animal cells.

190. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and frogs.

191. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[22]

192. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[23]

193. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. These studies consistently show increased risks of various cancers.

194. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, and pharynx cancer.[24]

[22] *Id.*
[23] *See* U.S. Envtl. Protection Agency, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.
[24] Straif et al., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Among a Cohort of Rubber Workers*, 57 Occup. Envtl. Med 180–87 (2000).

195. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers.[25]

196. NDMA is also known to be genotoxic—meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both in vivo and in vitro. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."[26]

197. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant (i.e., not malignant) tumor cells; (2) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

III. NDMA IS DISCOVERED IN RANITIDINE-CONTAINING PRODUCTS, LEADING TO MARKET WITHDRAWAL

198. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and ValisureRX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all ranitidine-containing products due to detecting exceedingly high levels of NDMA when testing ranitidine pills using gas chromatography-mass spectrometry. FDA and European regulators

[25] Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 Am. J. Clinical Nutrition 1053–61 (2011).
[26] World Health Org., *supra* note 16.

started reviewing the safety of ranitidine with specific focus on the presence of NDMA.[27] This set off a cascade of recalls by the Brand-Name Manufacturer, Generic Manufacturer, and Retailer Defendants.

199. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement warning that some ranitidine medicines may contain NDMA.[28]

200. On September 24, 2019, Sandoz voluntarily recalled all of its ranitidine-containing products due to concerns of a "nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine."

201. On September 26, 2019, Retailer Walgreens voluntarily recalled all ranitidine products and removed them from shelves.[29]

202. On September 26, 2019, Apotex voluntarily recalled all ranitidine products and removed them from shelves. Apotex issued a statement, noting that "Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)."

203. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using a liquid chromatography with high resolution mass spectrometer

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[27] FDA Statement, Woodcock, *supra* note 14; Press Release, European Medicines Agency, *EMA to Review Ranitidine Medicines Following Detection of NDMA* (Sept. 13, 2019), https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma.

[28] *Id.*

[29] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Sept. 26, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

("LC-HRMS") testing protocol, which "does not use elevated temperatures."[30] Retailer Walmart voluntarily recalled all of their OTC ranitidine products the same day.[31]

204. On October 8, 2019, GSK voluntarily recalled all ranitidine-containing products internationally.[32] As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that "GSK is continuing with investigations into the potential source of the NDMA."[33]

205. On October 18, 2019, Sanofi voluntarily recalled all of their ranitidine-containing products.[34]

206. On October 23, 2019, Dr. Reddy's voluntarily recalled all of their ranitidine-containing products.

207. On October 28, 2019, Lannett, Novitium, and Perrigo voluntarily recalled all their ranitidine-containing products.

208. Lannett also acknowledged the presence of NDMA in the drug product in its recall notice: "Lannett was notified by FDA of the potential presence of NDMA on September 17, 2019,

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[30] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[31] *Walmart Statement on the Sale of Ranitidine Products*, Walmart.com (Oct. 2, 2019), https://corporate.walmart.com/newsroom/2019/10/01/walmart-statement-on-the-sale-of-ranitidine-products.

[32] Press Release, Gov. UK, *Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls All Unexpired Stock* (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.

[33] Justin George Varghese, *GSK Recalls Popular Heartburn Drug Zantac Globally After Cancer Scare*, Reuters (Oct. 8, 2019), https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk-recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL.

[34] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 23, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

and immediately commenced testing of the Active Pharmaceutical Ingredient (API) and drug product. The analysis confirmed the presence of NDMA."

209. In its recall notice, Perrigo stated, "[a]fter regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall."

210. Between November 1, 2019, and February 27, 2020, Amneal, GSMS, and Glenmark recalled their products from the market, citing NDMA concerns.

211. On November 1, 2019, the FDA announced the results of recent testing, finding unacceptable levels of NDMA in ranitidine-containing products, and requested that drug makers begin to voluntarily recall their ranitidine-containing products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.[35]

212. On December 4, 2019, the FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, e.g., processed meats and preservatives like sodium nitrite.[36] This advice mirrored an admonition issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites in vitro to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. de Flora published in October 1981 in The Lancet was to "avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals or

[35] U.S. Food & Drug Admin., Laboratory Tests | Ranitidine, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine (content current as of Nov. 1, 2019).
[36] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Dec. 4, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

by giving inhibitors of nitrosation such as ascorbic acid."[37] If GSK had only heeded Dr. de Flora's advice in 1981, millions of people might have avoided exposure to NDMA formed as a result of ranitidine's interaction with the human digestive system.

213. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that the ranitidine molecule is heat-liable and under certain temperatures progressively accumulates NDMA.

214. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. Emery requested that the FDA issue a directive to manufacturers to clearly label ranitidine with a warning that "by-products that are probable carcinogens can be generated if exposed to heat." In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine products in temperature-controlled vehicles.[38]

215. In response,[39] on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health."[40] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."[41] The FDA found that the recall of all ranitidine-containing products and a public warning

[37] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, The Lancet, Oct. 31, 1981, at 993–94.
[38] Emery Pharma FDA Citizen Petition (Jan. 2, 2020) https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.
[39] Letter of Janet Woodcock, U.S. Food & Drug Admin., Docket No. FDA-2020-P-0042 (Apr. 1, 2020), *available at* https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf.
[40] *Id.* at 5 (*citing* 21 CFR 7.40(a)).
[41] *Id.*

of the recall was necessary because the "product being recalled presents a serious health risk."[42] The FDA therefore sent Information Requests to all applicants and pending applicants of ranitidine-containing products "requesting a market withdrawal."[43]

216. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine-containing products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed that higher NDMA levels were found as the products approached their expiration dates. The FDA's testing eroded the agency's confidence that any ranitidine-containing product would remain stable through its labeled expiration date. Consequently, the FDA requested a market withdrawal of all ranitidine products. The FDA also announced to the public that the Agency's laboratory tests indicate that temperature and time contribute to an increase in NDMA levels in some ranitidine products. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

217. The FDA's reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned ranitidine-containing products.[44]

218. The European Medicines Agency ("EMA"), the European Union's equivalent to the FDA, through an Article 31 Referral, determined the sale of all ranitidine-containing products should be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA "has recommended the suspension of all ranitidine medicines in the EU due to the

[42] *Id.* at 7.
[43] *Id.* at 10 n.43.
[44] Margaret Newkirk & Susan Berfield, *FDA Recalls Are Always Voluntary and Sometimes Haphazard—and The Agency Doesn't Want More Authority to Protect Consumers*, Bloomberg Businessweek (Dec. 3, 2019), https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

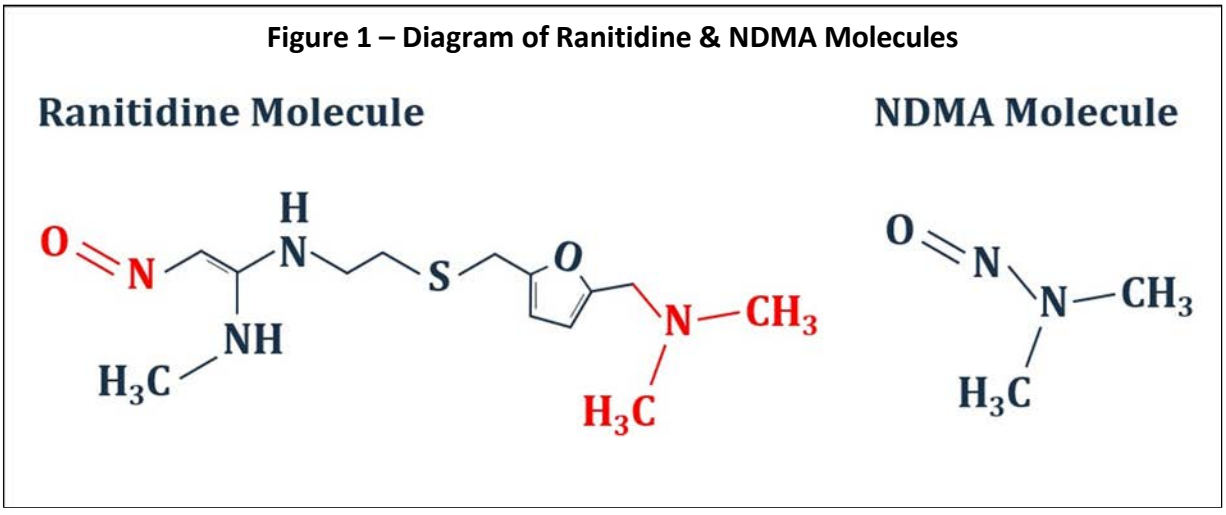
presence of low levels of an impurity called N-nitrosodimethylamine (NDMA)." The EMA recognizes NDMA as a probable human carcinogen and issued a "precautionary suspension of these medicines in the EU" because "NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities."[45]

219. On September 17, 2020, after a ranitidine manufacturer requested that the EMA re-examine its decision and permit ranitidine to be marketed again in the EU, the EMA confirmed its prior recommendation to suspend all ranitidine medicines in the EU due to the presence of NDMA noting that it is a probable human carcinogen and that there is evidence that NDMA forms from the degradation of ranitidine itself with increasing levels seen over shelf life.[46]

IV. HOW RANITIDINE TRANSFORMS INTO NDMA

220. The ranitidine molecule itself contains the constituent molecules to form NDMA. See Figure 1.

Figure 1 – Diagram of Ranitidine & NDMA Molecules



[45] Eur. Med. Agency, *Suspension of Ranitidine Medicines in the EU* (Apr. 30, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-suspension-ranitidine-medicines-eu_en.pdf.

[46] Eur. Med. Agency, EMA Confirms Recommendation to Suspend All Ranitidine Medicines in the EU (Nov. 24, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-ema-confirms-recommendation-suspend-all-ranitidine-medicines-eu_en.pdf.

221. The degradation occurs independently in two parts of the ranitidine molecule, with the products of the degradation combining to produce NDMA.

222. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the U.S. water supply.[47] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants were specifically linked to the presence of ranitidine.[48]

223. The high levels of NDMA observed in ranitidine-containing products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system, and when it interacts with nitrogenous products.

A. Formation of NDMA in the Environment of the Human Stomach

224. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (0=N) and the DMA molecule (H3C-N-CH3) break off and reform as NDMA.

225. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, The Lancet. When ranitidine was exposed to human gastric fluid in combination with nitrites, his

[47] Ogawa et al., *Purification and Properties of a New Enzyme, NG, NG-dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. Bio. Chem. 17, 10205–209 (1989).
[48] Mitch et al., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 Env. Eng. Sci. 5, 389–404 (2003).

experiment showed "toxic and mutagenic effects."[49] Dr. de Flora hypothesized that these mutagenic effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions."[50] Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to … suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals."[51]

226. GSK knew of Dr. de Flora's publication because, two weeks later, GSK responded in The Lancet, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (i.e., NDMA) were not likely to be experienced by people in the real world.[52]

227. This response reflects GSK's reputation for "adopting the most combative, scorched-earth positions in defense of its brands."[53] The company has no compunctions against distorting objective science to maintain its lucrative monopoly franchises, and its egregious conduct surrounding Zantac is not some isolated incident.

228. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. As we now know, the company was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. In the wake of Congressional hearings into

[49] De Flora, *supra* note 36.
[50] *Id.*
[51] *Id.* This admonition came two years before the FDA approved Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal." *See* Ctr. for Drug Eval. & Research, *Approval Package* (June 8, 1998), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1_Zantac.pdf. GSK thus specifically invited patients to take Zantac shortly before eating heartburn-inducing food.
[52] R. T., Brittain et al., *Safety of Ranitidine*, The Lancet 1119 (Nov. 14, 1981).
[53] Jim Edwards, *GSK's Alleged Coverup of Bad Avandia Data: A Snapshot of Its Poisonous Corporate Culture*, Moneywatch (July 13, 2010) https://www.cbsnews.com/news/gsks-alleged-coverup-of-bad-avandia-data-a-snapshot-of-its-poisonous-corporate-culture/.

the company's outrageous misbehavior,[54] GSK's actions resulted in a criminal investigation and the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety data in the country's history.[55] There is currently an open investigation of GSK and Sanofi being conducted by the Department of Justice relating to the failure to disclose to the federal government information about the potential presence of NDMA in Zantac.[56]

229. GSK attended an FDA Advisory Committee in May 1982 where its representative testified and presented evidence relating to the safety of Zantac, including the potential for ranitidine to form nitrosamines. However, GSK failed to disclose its new evidence relating to ranitidine and the formation of a nitrosamine, specifically the formation of NDMA.

230. One month later, in June 1982, GSK submitted its draft Summary Basis of Approval and labeling for Zantac. Again, GSK failed to submit or otherwise disclose its new evidence relating to ranitidine and the formation of NMDA.

231. In its submission to the FDA, GSK discussed its findings from internal studies performed in 1980 that ranitidine formed a different nitrosamine, n-nitroso-nitrolic acid, a potent mutagen, but explained that these results had no "practical clinical significance"[57]:

[54] *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance, 111th Cong.2d Sess. 1 (Comm. Print Jan. 2010).
[55] *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data*, U.S. Dep't of Justice (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.
[56] *Half-Year Financial Report*, Sanofi (2020), https://www.sanofi.com/dam/jcr:a0bbf303-2d28-44e9-a127-f4646d402a75/2020_07_29_HY_financial_report_EN.pdf.
[57] Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.

> Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

232. In 1980—before Zantac was approved by the FDA—GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach.[58] Remarkably, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of forming nitrosamines and, in turn, cancer, but then dismissed this risk because people were allegedly only expected to use ranitidine-containing products for a short-term period:

> The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

233. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form nitrosamines and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach. GSK also knew but did not disclose that it had new evidence showing that NDMA was generated by ranitidine under certain conditions.

[58] The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

234. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.[59] The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was flawed. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."[60] In other words, GSK intentionally engineered the study to exclude the very samples most likely to contain a dangerous carcinogen.

235. Given the above information that was disclosed relating to the nitrosation potential and formation of nitrosamines, it is shocking that GSK conducted an internal study to assess the formation of NDMA and found that ranitidine, when exposed to sodium nitrite, formed hundreds of thousands of nanograms of NDMA. The GSK study was never published or disclosed to the public.

236. In 1983, the same year GSK started marketing Zantac in the United States, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).[61] The researchers concluded "it appears that reaction of ranitidine

[59] Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 6 Gut. Vol. 28, 726–38 (1987).
[60] *Id.*
[61] Maura et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 Tox. Ltrs. 97–102 (1983).

with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells."[62]

237. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.[63] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine." Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." This admonition carries weight considering GSK's studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

238. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[64] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-treatment plants that supply many U.S. cities with water.

239. In 2016, researchers at Stanford University conducted an experiment on healthy adult volunteers.[65] They measured the NDMA in urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. The study reported that on average, the level of NDMA

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[62] *Id.*
[63] De Flora et al., *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255–60 (1983).
[64] Le Roux et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 Envtl. Sci. Tech. 20, 11095–103 (2012).
[65] Zeng et al., *Oral intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*, 37 Carcinogenesis 625–34 (2016).

increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. In the study, the scientists further explained that previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. This study showed that ranitidine generates NDMA in the human body.

240. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO")—an accreditation recognizing the laboratories technical competence for regulatory purposes. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

241. In its September 9, 2019, Citizen's Petition to the FDA,[66] Valisure disclosed as part of its testing of ranitidine-containing products that in every lot tested there were exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.[67] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol		
150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798

[66] Valisure, *Citizen Petition on Ranitidine* (Sept. 9, 2019), *available at* https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf.

[67] U.S. Food & Drug Admin., *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).

Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, Strides	77024060A	2,951,649

242. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures.

243. Valisure was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

244. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF": 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF": 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

245. Indeed, ranitidine-containing products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.[68]

[68] *See, e.g.*, Zantac television commercial, *Family Taco Night*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; Zantac television commercial, *Spicy*, https://youtu.be/jzS2kuB5_wg; Zantac television commercial, *Heartburn*, https://youtu.be/Z3QMwkSUlEg; Zantac television commercial, *Zantac Heartburn Challenge*, https://youtu.be/qvh9gyWqQns.

246. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (see Table 2).

Table 2 – Valisure Biologically Relevant Tests for NDMA Formation		
Ranitidine Tablet Studies	NDMA (ng/mL)	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid ("SIF")	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

247. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg ranitidine, ranging between 245 and 3,100 times above the FDA-allowable limit. One would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg ranitidine at the 25 nanogram level (over 7,000 for the 50 nanogram level).

248. Following the release of Valisure Citizen's Petition, the FDA conducted additional laboratory tests, which showed NDMA levels in all ranitidine samples it tested, including API and the finished drug, both tablets and syrup. The FDA developed simulated gastric fluid ("SGF") and simulated intestinal fluid ("SIF") models to use with the LC-MS testing method to estimate the biological significance of in vitro findings. These models are intended to detect the formation of NDMA in systems that approximate the stomach and intestine.

249. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine already containing NDMA combined with the presence of human-relevant levels of nitrite in the stomach—a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month—the ranitidine

molecule transforms into more NDMA which would dramatically increase a person's risk of developing cancer.

B. Formation of NDMA in Other Organs of the Human Body

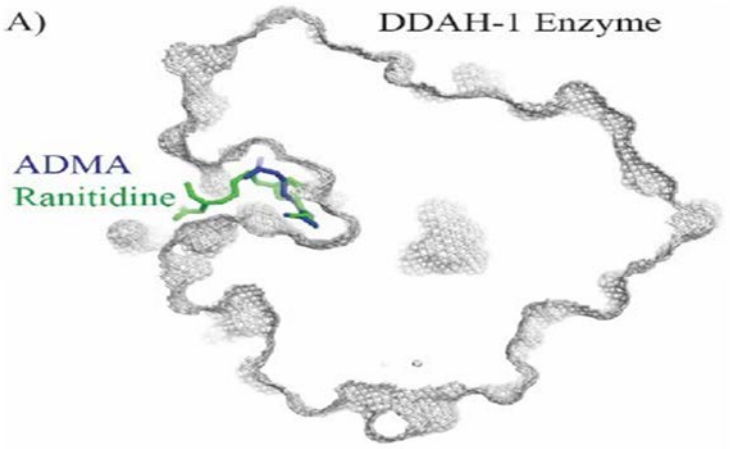
250. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach.

251. Valisure explained that liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[69]

[69] Ogawa, *et al.*, *supra* note 46.

252. Valisure reported as illustrated in Figure 2 computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

Figure 2 – Computational Modelling of Ranitidine Binding to DDAH-1 Enzyme

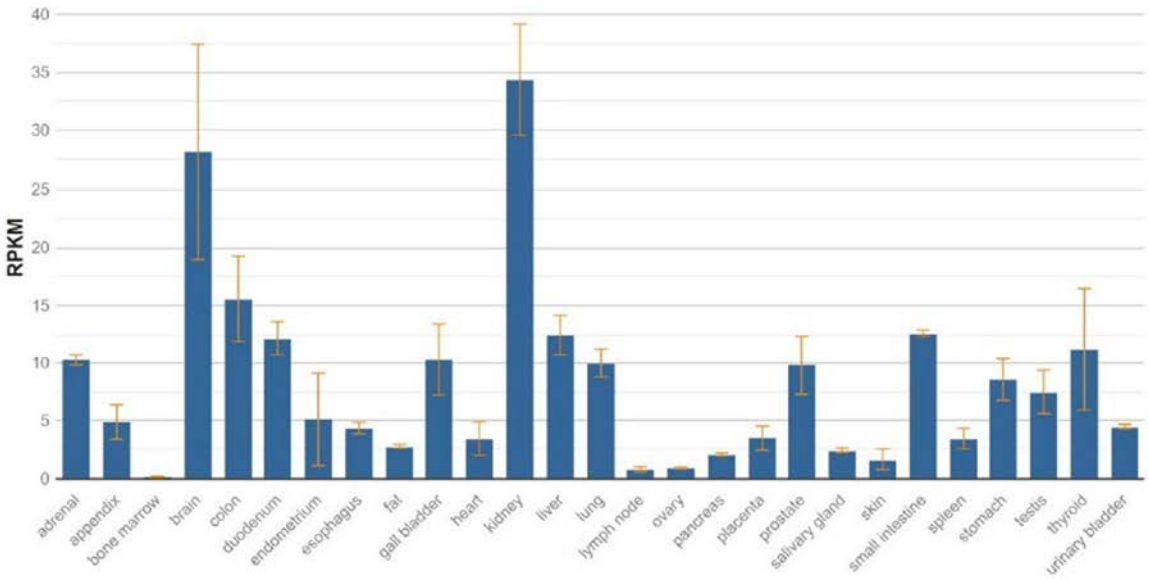


	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

253. Valisure reported that these results suggest that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

254. Figure 3 derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.

Figure 3 – Expression levels of DDAH-1 enzyme by Organ



255. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the brain, colon, liver, small intestine, stomach, bladder, and prostate. Valisure noted that this offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs.

256. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1 to 2 hours. When ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study, discussed above.

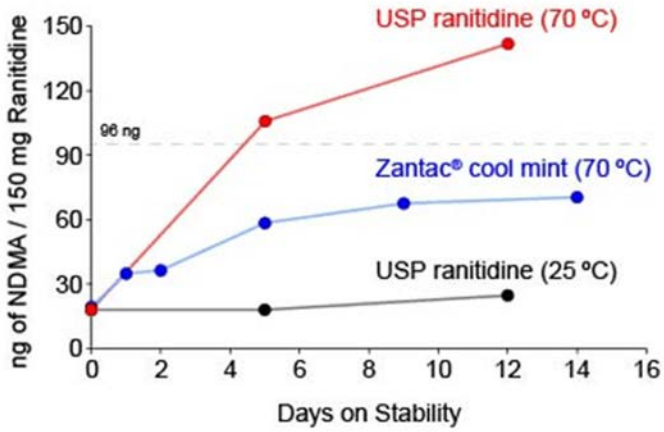
C. Formation of NDMA by Exposure to Heat, Moisture, and/or Time

257. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that nitrosamines were formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high-heat testing method.

258. In response to Valisure, on October 2, 2019, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the "testing method does not use elevated temperatures" and has been proven capable of detecting NDMA.

259. On January 2, 2020, Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 ◦C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. As reported by Emery Pharma, the following diagram reveals how NDMA accumulates over time when exposed to 70 ◦C:

Figure 4 – Rate of Development of NDMA when Exposed to Heat



260. The researchers cautioned:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during

> storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.[70]

261. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks down into NDMA, accumulating over time in the finished product. Considering ranitidine-containing products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is very real—a point underscored by the FDA's swift removal of the product from the market.

262. In fact, the FDA acknowledged that testing revealed that NDMA levels in ranitidine products stored at room temperature can increase with time to unacceptable levels.

263. In 2019, the findings by Valisure unleashed an avalanche of regulatory authorities throughout the world demanding that the manufacturers of Zantac and/or ranitidine conduct testing of their products for the presence of NDMA as well as investigate the root cause as to how NDMA was being generated. In April 2020, the FDA requested that manufacturers immediately remove all ranitidine-containing products from the market.

264. In the interim between the Valisure findings being released to the public and the FDA announcement requesting recall of all ranitidine products in April 2020, the manufacturers were investigating the root cause of NDMA in their products.

265. After undertaking an investigation, GSK concluded that "the presence of NDMA in ranitidine drug substance is due to a slow degradation reaction occurring primarily in the solid state. The two constituent parts of NDMA, the nitroso group and the dimethylamino group, are

[70] Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 2, 2020), *available at* https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.

both derived from internal degradation reactions which occur at slow rates with the ranitidine molecule."

266. Both Brand and Generic Defendants could dictate the conditions under which API was transported to them. The labeling requirements do not apply to transporting API, in part because the finished product and API are packaged differently and may degrade under different conditions.

267. Based upon the documents produced by Defendants and based upon further information and belief, both the Brand and Generic Defendants failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were kept safely from excessive heat and humidity.

V. EVIDENCE DIRECTLY LINKS RANITIDINE EXPOSURE TO PLAINTIFFS' CANCER

268. In addition to numerous epidemiology studies examining how NDMA causes cancer in humans, researchers have also specifically looked at ranitidine and found an association with numerous cancers.

269. In one epidemiological study looking at various cancer risks and histamine H2-receptor antagonists (or H2 blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.[71]

270. A number of studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H2 blockers.[72] Research reports have

[71] Laurel A Habel et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 Pharmacoepidemiology & Drug Safety 149–55 (2000).

[72] Robert W. Mathes et al., *Relationship Between Histamine2-receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 Cancer Epi. Biomarkers & Prevention 1, 67–72 (2008); *see also* Jeong Soo Ahn et al., *Acid Suppressive Drugs and Gastric Cancer: A Meta-analysis of Observational Studies*, 19 World J. Gastroenterology 16, 2560 (2013); Shih-Wei Lai et al., *Use of Proton Pump Inhibitors Correlates with Increased Risk of Pancreatic Cancer: A Case-control*

shown that ranitidine use was associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.[73]

VI. MANUFACTURER DEFENDANTS KNEW OR SHOULD HAVE KNOWN OF THE NDMA RISK

271. As early as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested.[74] This was known or should have been known by all Defendants as the information was available in medical literature.

272. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.[75] Many metabolites were listed, though there is no indication that the study looked for NDMA.

273. Indeed, in that same year, Dr. de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites—a substance commonly found in food and in the body.[76] GSK was aware of this study because GSK specifically responded to the note and attempted to discredit it. Manufacturer Defendants knew or should have known about this scientific exchange as it was published in a popular scientific journal. Manufacturer Defendants were obligated to investigate this issue properly. None did.

Study in Taiwan, 46 Kuwait Med J. 1, 44–48 (2014); Poulsen et al., *Proton Pump Inhibitors and Risk of Gastric Cancer – A Population Based Cohort Study*, 100 Brit. J. Cancer 1503–07 (2009); E Wennerström, *Acid-suppressing Therapies and Subsite-specific Risk of Stomach Cancer*, 116 Brit. J. Cancer 9, 1234–38 (2017).

[73] Richard H. Adamson & Bruce A. Chabne, *The Finding of N-Nitrosodimethylamine in Common Medicines*, The Oncologist, June 2020; 25(6): 460–62, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7288647/.

[74] *See supra* ¶ 173 (discussing de Flora research).

[75] Carey et al., *Determination of Ranitidine and Its Metabolites in Human Urine by Reversed-phase Ion-pair High-performance Liquid Chromatography*, 255 J. Chromatography B: Biomedical Sci. & Appl. 1, 161–68 (1981).

[76] De Flora, *supra* note 36.

274. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[77] That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was flawed. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Not only is that approach not accurate, but GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was knowable in light of its scientific publication in 1987. All Defendants either knew or should have known about the inadequacy of that study and should have investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products. None did.

THE FEDERAL REGULATORY LANDSCAPE

275. Plaintiffs' reference federal law herein not in any attempt to enforce it, but only to demonstrate that their Illinois tort claims do not impose any additional obligations on Defendants, beyond what is already required of them under federal law.

[77] Thomas et al., *supra* note 57.

I. BRAND AND GENERIC MANUFACTURER DEFENDANTS MADE FALSE STATEMENTS IN THE LABELING OF RANITIDINE-CONTAINING PRODUCTS

276. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[78] and conform to requirements governing the appearance of the label.[79]

277. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[80] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

278. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[81]

279. All drug manufacturers (brand and generic) are also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products."[82] Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."[83]

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[78] 21 C.F.R. § 201.5.
[79] *Id.* § 201.15.
[80] *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).
[81] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[82] 21 C.F.R. § 211.166(a).
[83] *Id.*

280. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates."[84] And expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use." An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in § 211.166."[85]

281. Notably, while generic medications must have the same active ingredients as their branded counterparts, the inactive ingredients, or excipients, may not necessarily be identical. For this reason, the stability of each generic drug may differ from manufacturer to manufacturer, or even from manufacturing process to manufacturing process.

282. Each manufacturer, whether brand or generic, must therefore conduct its own tests to determine and set accurate retest or expiration dates.

283. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[86]

284. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf-life studies, there must be stability studies

[84] *Id.*
[85] *Id.* § 211.137(a).
[86] 43 Fed. Reg. 45059 (Sept. 29, 1978).

conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."[87]

285. After a drug is approved, a manufacturer (brand or generic) can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§ 314.70 and 314.71.[88]

286. Some of the requirements in those regulations require a brand or generic manufacturer of an approved drug to obtain FDA approval before implementing a label change.[89]

287. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.[90]

288. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[91] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."[92]

289. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date—which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"[93]—or to ensure that the drug is shipped and stored under appropriate conditions.

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[87] 21 C.F.R. § 211.166(b).
[88] *See id.* § 314.97(a) (requiring generics to comply with §§ 314.70, 314.71).
[89] *Id.* § 314.70(b).
[90] *Id.* § 314.70(c)(3), (c)(6).
[91] *Id.* § 314.70(c)(6)(i).
[92] 65 Fed. Reg. 83042 (Dec. 29, 2000).
[93] 21 C.F.R. § 211.137(a).

290. A manufacturer of an approved drug can also use the CBE supplement to make "moderate" changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."[94]

291. Thus, Brand Manufacturers could have made these changes to their several NDAs for Zantac. Any change GSK made to its Zantac label to strengthen warnings when it first held the NDAs 20-520 and 20-745 would have been passed to Pfizer, BI, and Sanofi when they took over the NDAs. Similarly, any change Pfizer made to its Zantac label to strengthen warnings when it first held the NDAs 20-520, 20-745, and 21-698 would have been passed to BI and Sanofi when they took over the NDAs. Any change BI made to its Zantac label to strengthen warnings when it held the NDAs 20-520, 20-745, and 21-698 would have been passed to Sanofi when it took over the NDAs. Finally, Sanofi had the power to change the labels and warnings for all drugs under OTCs 20-520, 20-745, and 21-698 when it controlled the NDAs.

292. Also, at no time did the Manufacturer Defendants, in concert or individually, seek to make a change to the labels and warnings of OTC Zantac to warn about the risk of cancer associated with NDMA. However, they did seek to make CBE regulation changes to all of these NDAs for other commercial purposes, which were approved by the FDA.

[94] *Id.* § 314.70(c)(6)(iii)(A), (C), (D).

293. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."[95]

294. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf-life data on production batches obtained from a protocol approved in the NDA."[96]

295. At no time did any Brand-Name Manufacturer attempt to include a warning on the labels for ranitidine-containing products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

296. At no time did any Manufacturer Defendant attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that ranitidine-containing products would not break down into NDMA prior to human consumption.

297. Based on the public scientific information, the Manufacturer Defendants knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

298. At no time did any Manufacturer Defendant change its label to shorten the expiration date. Manufacturer Defendants had the ability to unilaterally make such label changes

[95] *Id.* § 314.70 (d)(2)(ix).
[96] *Id.* § 314.70 (d)(2)(vi); *see also id.* § 314.70(d)(2)(vii), (x).

(for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any Manufacturer Defendant attempted such label changes, the FDA would not have rejected them.

299. Because they failed to include appropriate expiration dates on their products, Manufacturer Defendants made false statements in the labeling of their products.

II. GENERIC MANUFACTURER REQUIREMENTS

300. According to FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as its brand-name version. In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."[97]

301. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an ANDA. As the first "A" in ANDA denotes, the generic approval process is "abbreviated" to serve Congress's intent to expeditiously offer consumers lower-cost, previously approved medicines. But the abbreviated NDA process does not absolve generic manufacturers of their obligations to ensure that their drugs are safe and effective. To obtain FDA approval, an ANDA applicant must demonstrate that the generic medicine is the same as the brand-name version in the following ways:

a. The active ingredient in the generic medicine is the same as in the brand-name drug/innovator drug.

[97] U.S. Food & Drug Admin., *Generic Drugs: Questions & Answers U.S. Food and Drug Administration*, https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers (current as of June 1, 2018).

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

e. The container in which the medicine will be shipped and sold is appropriate.[98]

302. Because the brand-name manufacturer previously demonstrated clinical safety and efficacy when the NDA was approved, an ANDA applicant does not need to do so if it can show bioequivalence to the branded, reference listed drug ("RLD"). Bioequivalence is the "absence of a significant difference" in the pharmacokinetic profiles of two pharmaceutical products.[99]

303. Though an ANDA applicant's drug must be bioequivalent to the RLD, no two manufacturers' drugs will be exactly the same. For that reason, generic manufacturers are responsible for conducting their own, independent stability testing, which must be "designed to assess the stability characteristics of drug products."[100]

304. Because a generic manufacturer's drug must be bioequivalent to the RLD, a compliant generic label should be "the same as the labeling of the reference listed drug" in many respects.[101] But because a generic drug may not be exactly the same as the RLD, the generic label "may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance."[102]

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[98] U.S. Food & Drug Admin., *Generic Drug Facts*, https://www.fda.gov/drugs/generic-drugs/generic-drug-facts (current as of June 1, 2018).
[99] 21 C.F.R. §§ 320.1(e) & 314.3(b).
[100] *Id.* § 211.166(a).
[101] *Id.* § 314.94(a)(8)(iii).
[102] *Id.* § 314.94(a)(8)(iv).

This regulation by its terms does not apply to non-label elements of a generic drug, including the container and number of units.

305. Pursuant to this regulation, it is common for a generic drug's label to differ from the RLD by setting a different expiration date, requiring the drug to be shipped and stored under different temperature conditions, and/or requiring the drug to receive different (or no) exposure to light. Several of the Generic Defendants relied on 21 C.F.R. § 314.94(a)(8)(iv) and their independent stability studies to sell approved, generic ranitidine with labels that differed from the RLD label.

III. FEDERAL LAW REQUIRED THE MANUFACTURER DEFENDANTS TO NOTIFY THE FDA ABOUT THE PRESENCE OF NDMA IN RANITIDINE-CONTAINING PRODUCTS

306. During the time that Manufacturer Defendants manufactured and sold ranitidine-containing products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. Manufacturer Defendants failed to report these risks to the FDA.

307. Manufacturer Defendants concealed the ranitidine–NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

308. Manufacturers (brand and generic) of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this

> new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

309. 21 C.F.R. § 314.81(b)(2)(v) provides that the manufacturer's annual report must also contain:

> Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

310. Manufacturer Defendants ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in their products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of ranitidine-containing products.

311. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any manufacturer, consistent with its heightened obligations to ensure the safety of its products, also should have known about the potential NDMA risks associated with ranitidine consumption.

312. Manufacturer Defendants never conducted or provided the relevant studies to the FDA, nor did they present the FDA with a proposed disclosure noting the various ways that ranitidine transforms into NDMA. Accordingly, because Manufacturer Defendants never properly disclosed the risks to the FDA, they never proposed any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for transport / storage.

313. When the FDA eventually learned about the NDMA risks posed by ranitidine-containing products, it ordered manufacturers to voluntarily remove the products from the market. Thus, had any Manufacturer Defendant alerted the FDA to the risks of NDMA, the FDA would have required the manufacturers to remove ranitidine-containing products from the market.

IV. GOOD MANUFACTURING PRACTICES

314. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards.[103]

315. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

316. Pursuant to 21 C.F.R. § 211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse ranitidine.

317. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.[104] FDA has also concluded that NDMA can increase in ranitidine under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling. FDA's testing also showed that the level of NDMA in ranitidine-containing products increases with time. And while Emery's Citizen Petition sought to obtain a directive regarding temperature-

[103] 21 U.S.C. § 351(a)(2)(B).
[104] Woodcock Letter, *supra* note 38.

controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw ranitidine-containing products altogether.

318. Nothing prevented any Defendant from, on their own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring that ranitidine was not exposed to heat or moisture over long periods.

V. RETAILER ALLEGATIONS

A. Walgreens

319. Walgreens offers store-brand drugs, which are low-priced alternatives to name-brand products. Walgreens has numerous store brands.

320. At all pertinent times, Walgreens sold Zantac and Wal-Zan, a generic ranitidine marketed and sold under Walgreens' store brand label. Zantac and Wal-Zan were available for sale at Walgreens stores throughout the United States, including 574 stores in Illinois.

321. An example of a Wal-Zan label for Walgreens' store brand ranitidine follows:

322. Walgreens is a PLD with respect to many of the OTC medications it sells, including Wal-Zan. As a result, Walgreens contracted with third-party manufacturers to manufacture Wal-Zan.

323. According to FDA's National Drug Code Directory, Walgreens contracted with Perrigo, Dr. Reddy's Laboratories, Apotex, and Strides to manufacture its Wal-Zan ranitidine products.

324. With respect to OTC medications, Walgreens is considered a Private Label Distributor (PLD). As a PLD, Walgreens is responsible for ensuring that all of its products (a) comply with cGMPs, (b) are not adulterated for failure to comply with cGMPs, and (c) are not misbranded.

325. Walgreens says that its "products . . . are rigorously analyzed for compliance with all applicable laws and regulations" as well as Walgreens' "own higher standards," and that its "own product safety analysis" sometimes "come to a different, stricter conclusion than some regulatory bodies." (emphasis added).

326. Walgreens states that it understands that "consumers want to feel confident the products they use are safe for their intended purposes."

327. According to Walgreens, "[p]atient safety lies at the heart of our management of pharmacy operations, and we strive to be the industry leader by continuously seeking ways to minimize risks to patients in our dispensing, pharmacy services and advance and pharmacy supply chain operations."

328. Walgreens has admitted that it seeks to make its store brand OTC products "slightly better than the national brand" by tinkering with the "product format" such as the product container.

329. A reasonably prudent PLD would have changed the containers for ranitidine containing products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

330. Walgreens had a duty to monitor for and/or discover defects in its ranitidine products.

331. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." Walgreens thus had a duty and was obligated to properly store, handle, and warehouse ranitidine.

332. Nothing prevented Walgreens from, on its own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Walgreens from ensuring that ranitidine was not exposed to humidity or moisture.

333. Based on the public scientific information, Walgreens knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA. In addition, Walgreens knew or should have known that exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or the passage of time can cause the ranitidine molecule to degrade into NDMA. Accordingly, Walgreens knew or should have known, based on the extensive scientific, medical, and regulatory information discussed above, that ranitidine could potentially contain deadly NDMA.

334. Nevertheless, Walgreens allowed its ranitidine products to be subjected to high temperatures and humidity during storage and transport, sold its ranitidine products in large quantities of up to 200 tablets thus increasing the time period that consumers would be likely to store the product, and selected bottles for packaging that exacerbated ranitidine degradation as compared to blister packs or similar individually packaged containers.

335. As a result of such exposure, Walgreens was aware or should have been aware that ranitidine use substantially increases the risk for developing various cancers.

336. Because Walgreens failed to package its products in appropriate container sizes, they had an unsafe design and were unreasonably dangerous.

337. Walgreens' conduct, as described above, was reckless. Walgreens regularly risked the lives of consumers and users of their products with full knowledge of the dangers of its products.

B. Walmart

338. Walmart offers store-brand drugs, which are low-priced alternatives to name-brand products. Walmart has numerous store brands.

339. At all pertinent times, Walmart sold Zantac and a generic ranitidine marketed and sold under Walmart's store brand label, Equate. Zantac and Equate ranitidine were available for sale at Walmart stores throughout the United States, including 160 stores in Illinois.

340. An example of a label for Walgreens' store brand ranitidine follows:

341. Walmart is a PLD with respect to many of the OTC medications it sells, including Equate ranitidine. As a result, Walmart contracted with third-party manufacturers to manufacture ranitidine.

342. With respect to OTC medications, Walmart is considered a Private Label Distributor (PLD). As a PLD, Walmart is responsible for ensuring that all of its products (a) comply with cGMPs, (b) are not adulterated for failure to comply with cGMPs, and (c) are not misbranded.

343. Walmart says that it is "commit[ted] to integrity" and works to "ensur[e] the food and products we sell are safe." Walmart is "committed to the health and safety of our customers and members and to providing products that are safe and compliant."

344. A reasonably prudent PLD would have changed the containers for ranitidine containing products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

345. Walmart had a duty to monitor for and/or discover defects in its ranitidine products.

346. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." Walmart thus had a duty and was obligated to properly store, handle, and warehouse ranitidine.

347. Nothing prevented Walmart from, on its own, taking actions to prevent accumulation of NDMA in ranitidine-containing products by ensuring storage and transport at the lower end of the temperature range contained on the labels. Nothing prevented Walmart from ensuring that ranitidine was not exposed to humidity or moisture.

348. Based on the public scientific information, Walmart knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA. In addition, Walmart knew or should have known that exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or the passage of time can cause the ranitidine molecule to degrade into NDMA. Accordingly, Walmart knew or should have known, based on the extensive scientific, medical, and regulatory information discussed above, that ranitidine could potentially contain deadly NDMA.

349. Nevertheless, Walmart allowed its ranitidine products to be subjected to high temperatures and humidity during storage and transport, sold its ranitidine products in large quantities of over 200 tablets thus increasing the time period that consumers would be likely to store the product, and selected bottles for packaging that exacerbated ranitidine degradation as compared to blister packs or similar individually packaged containers.

350. As a result of such exposure, Walmart was aware or should have been aware that ranitidine use substantially increases the risk for developing various cancers.

351. Because Walmart failed to package its products in appropriate container sizes, they had an unsafe design and were unreasonably dangerous.

352. Walmart's conduct, as described above, was reckless. Walmart regularly risked the lives of consumers and users of their products with full knowledge of the dangers of its products.

VI. RANITIDINE-CONTAINING PRODUCTS ARE MISBRANDED AND ADULTERATED BECAUSE THEY CONTAIN DANGEROUS AND BIOLOGICALLY RELEVANT LEVELS OF NDMA

353. The manufacture of any misbranded or adulterated drug is prohibited under federal law.[105]

354. The introduction into commerce of any misbranded or adulterated drug is similarly prohibited.[106]

355. Similarly, the receipt in interstate commerce of any adulterated or misbranded drug is also unlawful.[107]

[105] 21 U.S.C. § 331(g).
[106] *Id.* § 331(a).
[107] *Id.* § 331(c).

356. Among the ways a drug may be adulterated and/or misbranded is: "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[108]

357. As recent regulatory action confirms, ranitidine was dangerous to health when used as prescribed.

358. It is unlawful to introduce a misbranded drug into interstate commerce.[109] Thus, the ranitidine ingested by Plaintiffs was unlawfully distributed and sold.

359. Because Defendants did not disclose NDMA as an ingredient in Zantac ingested by Plaintiffs, the subject drugs were misbranded.

360. Because Defendants did not disclose the proper directions for storage of the Zantac ingested by Plaintiffs, the subject drugs were misbranded.

361. Because Defendants did not disclose the proper directions for expiration of the Zantac ingested by Plaintiffs, the subject drugs were misbranded.

362. It is unlawful to introduce a misbranded drug into interstate commerce.[110] Thus, the Zantac ingested by Plaintiffs was unlawfully distributed and sold.

363. The generic ranitidine that Plaintiffs consumed used the same defective label devised by GSK originally and adopted from GSK by Pfizer, Boehringer Ingelheim, and Sanofi.

DEFENDANTS' WARRANTIES TO PLAINTIFFS

I. WARRANTIES COMMON TO MANUFACTURER DEFENDANTS

364. Each Manufacturer Defendant's ranitidine-containing product is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved label, Manufacturer

[108] 21 U.S.C. § 352(j).
[109] *Id.* § 331(a).
[110] *Id.* § 331(a).

Defendants made representations and express or implied warranties to consumers like Plaintiffs that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded.

365. In addition, each Manufacturer Defendant affirmatively misrepresented and warranted to physicians and patients like Plaintiffs through their websites, brochures, and other marketing or informational materials that their ranitidine-containing products complied with CGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels.

366. The presence of NDMA in Manufacturer Defendants' ranitidine-containing products resulted in Manufacturer Defendants' ranitidine-containing products containing an ingredient that is not also listed on each Defendant's FDA-approved label, breaching warranties listed on each Defendant's FDA-approved label and Defendants' express warranty of compliance. Each Manufacturer Defendant willfully, recklessly, or negligently failed to ensure their products' labels and other advertising or marketing statements accurately conveyed information about their products.

367. At all relevant times, Manufacturer Defendants have also impliedly warranted that their ranitidine-containing products were merchantable and fit for their ordinary purposes.

368. Due to its status as a probable human carcinogen as listed by both the IARC and the EPA, NDMA is not an FDA-approved ingredient. The presence of NDMA in Manufacturer Defendants' ranitidine-containing products means that Manufacturer Defendants violated implied warranties to Plaintiffs. The presence of NDMA in Manufacturer Defendants' products results in

their being non-merchantable and not fit for their ordinary purposes, breaching Manufacturer Defendants' implied warranty of merchantability and/or fitness for ordinary purposes.

369. For these and other reasons, Manufacturer Defendants' ranitidine-containing products are adulterated and/or misbranded, and it was illegal for Brand-Name Manufacturer and Generic Manufacturer Defendants to have introduced such ranitidine into commerce in the United States.[111]

II. WARRANTIES COMMON TO ALL NON-MANUFACTURING DEFENDANTS

370. By selling drugs in the stream of commerce, each Retailer Defendant warranted to consumers that the ranitidine-containing products they sold were safe and effective.

TOLLING / FRAUDULENT CONCEALMENT

371. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

372. Plaintiffs did not learn, nor could they have reasonably learned, of the link between their cancer and ranitidine exposure until on or around April 2020.

373. Plaintiffs would not have taken ranitidine had they known of or been fully and adequately informed by Defendants of the true increased risks and serious dangers of taking the drugs.

374. Upon information and belief, Plaintiffs' physicians were unaware of the increased risk of multiple types of cancer associated with the use of ranitidine due to its transformation into NDMA and, if they had been informed, would have used and prescribed alternative therapies to Plaintiffs.

[111] *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B), 331(g).

375. Plaintiffs' physicians would have changed the way in which they treated Plaintiffs' relevant conditions, changed the way they warned Plaintiffs about the signs and symptoms of serious adverse effects of ranitidine, and discussed with Plaintiffs the true risks of cancer, had Defendants provided Plaintiffs' physicians with an appropriate and adequate warning regarding the risks associated with the use of Zantac.

376. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts that they had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

377. Plaintiffs joined the Zantac/ranitidine multidistrict litigation registry by completing a Census Plus Form ("CPF") and signing the CPF certification. Participation in the registry tolled the applicable statute of limitations as of the date Plaintiffs' CPF were uploaded. *See In re Zantac (Ranitidine) Products Liability Litigation*, MDL No. 2924, Pretrial Order No. 15 at 11.

378. Plaintiffs joined the registry within the prescribed time limit following Plaintiffs' injuries and Plaintiffs' knowledge of the wrongful cause. Prior to such time, Plaintiffs did not know and had no reason to know of their injuries and/or the wrongful cause of those injuries.

379. Plaintiffs originally filed actions in various Illinois circuit courts. The Illinois Supreme Court ordered the actions consolidated and transferred to Cook County under Rule 384. On February 16, 2023, the Honorable Judge Trevino ordered Plaintiffs to file the instant Master Complaint. Hearing Tr. at 26:4-9 (Feb. 16, 2023).

380. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiffs and

defects associated with ranitidine-containing products as they transform into NDMA. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of ranitidine. As a result of Defendants' misrepresentations and concealment, Plaintiffs was unaware and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions, that they had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

381. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Plaintiffs could not reasonably have known that Defendants' ranitidine-containing products were and are defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY—FAILURE TO WARN
(Against All Manufacturer Defendants)

382. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

383. This Count alleges a claim by Plaintiffs for ranitidine Plaintiffs consumed and that each Defendant manufactured or sold while controlling the approved New Drug Application.

384. A manufacturer or seller has a duty to adequately warn of the potential risks or hazards associated with a product where there is unequal knowledge, actual or constructive, of a dangerous condition, and the defendant, possessed of such knowledge, knows or should know that harm might or could occur if no warning is given.

385. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of Defendants.

386. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their ranitidine-containing products, and in the course of same, directly marketed the products to consumers and end users, including Plaintiffs, and therefore had a duty to warn of the risks associated with the use of ranitidine.

387. At all relevant times, Defendants had a duty to properly design, manufacture, test, market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps as necessary to ensure their ranitidine-containing products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs of dangers associated with ranitidine. Defendants, as a manufacturer or seller of pharmaceutical medication, are held to the knowledge of an expert in the field.

388. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper expiration and retest dates, as well as the packaging, storage, and handling of ranitidine.

389. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

390. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by Defendants' ranitidine-containing products.

391. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiffs.

392. Defendants knew or should have known that ranitidine-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and physicians of the risks of exposure to ranitidine-containing products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

393. At all relevant times, Defendants' ranitidine-containing products were expected to and did reach Plaintiffs without a substantial change in their anticipated or expected design as manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants.

394. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics.

395. At all relevant times, Plaintiffs used and/or was exposed to the use of Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

396. Plaintiffs could not have reasonably discovered the defects and risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and Plaintiffs' physicians relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

397. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

398. The information that Defendants did provide or communicate failed to contain relevant warnings, expiration dates, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine-containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

399. This alleged failure to warn is not limited to the information contained on ranitidine-containing products' labeling. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with ranitidine through other non-labeling mediums, e.g., promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any medium.

400. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs could not have averted their injuries.

401. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

402. Defendants' lack of adequate warnings and instructions accompanying their ranitidine-containing products were a substantial factor in causing Plaintiffs' injuries.

403. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs were injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT II: STRICT PRODUCTS LIABILITY—DESIGN DEFECT
(Against All Defendants)

404. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

405. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, thereby placing ranitidine-containing products into the stream of commerce. These actions were under the ultimate control and supervision of these Defendants.

406. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold the ranitidine-containing products used by Plaintiffs, as described herein.

407. At all relevant times, Defendants' ranitidine-containing products were designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public.

408. At all relevant times, the medication ingested by Plaintiffs were expected to and did reach Plaintiffs without a substantial change in their anticipated or expected design as manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by the Manufacturer Defendants.

409. Defendants' ranitidine-containing products, as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants were

defective in design and formulation in that, when they left Defendants' control, they were unreasonably dangerous, and dangerous to an extent beyond that which an ordinary consumer would contemplate because of their inherent susceptibility to form NDMA.

410. Defendants' ranitidine-containing products, as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants were defective in design and formulation in that, when they left the hands of Defendants, the foreseeable risks exceeded the alleged benefits associated with their design and formulation because of their inherent susceptibility to form NDMA.

411. At all relevant times, Defendants knew or had reason to know that ranitidine-containing products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

412. Therefore, at all relevant times, Defendants' ranitidine-containing products, as designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by Defendants were defective in design and formulation, in one or more of the following ways:

a. Defendants' ranitidine-containing products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner;

b. Defendants' ranitidine-containing products were not reasonably safe when used in a reasonably anticipated or intended manner;

c. Defendants did not sufficiently test, investigate, or study their ranitidine-containing products and, specifically, the ability for ranitidine to transform into the carcinogenic compound NDMA within the human body;

d. Defendants did not sufficiently test, investigate, or study their ranitidine-containing products and, specifically, the stability of ranitidine and the ability for ranitidine-containing products to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

e. Defendants failed to provide accurate expiration dates on the product label;

f. Defendants failed to package their ranitidine-containing products in a manner which would have preserved the safety, efficacy, quality, and purity of the product;

g. Defendants failed to provide accurate instructions concerning the stability of the drug, including failing to provide accurate information about proper temperature and light conditions for storage of the drug;

h. Defendants knew or should have known at the time of marketing ranitidine-containing products that exposure to ranitidine could result in cancer and other severe illnesses and injuries;

i. Defendants did not conduct adequate post-marketing surveillance of their ranitidine-containing products;

j. Defendants did not conduct adequate stability testing of their product to ascertain shelf life, expiration, and proper storage, heat, and light specifications; and

k. Defendants could have employed safer alternative designs and formulations.

413. Plaintiffs used and were exposed to Defendants' ranitidine-containing products without knowledge of ranitidine's dangerous characteristics.

414. At all times relevant to this litigation, Plaintiffs used and/or were exposed to the use of Defendants' ranitidine-containing products in an intended or reasonably foreseeable manner without knowledge of ranitidine's dangerous characteristics.

415. Plaintiffs could not reasonably have discovered the defects and risks associated with ranitidine-containing products before or at the time of exposure due to Defendants' suppression or obfuscation of scientific information linking ranitidine to cancer.

416. Exposure to ranitidine presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug. The harm caused by Defendants' ranitidine-containing products far outweighed their benefit, rendering each Defendants' product dangerous

to an extent beyond that which an ordinary consumer would contemplate. Defendants' ranitidine-containing products were and are more dangerous than alternative products.

417. Defendants' defective design of ranitidine-containing products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of ranitidine-containing products, including Plaintiffs.

418. The defects in Defendants' ranitidine-containing products were substantial factors in causing Plaintiffs' injuries.

419. As a direct and proximate result of Defendants' defective design of ranitidine-containing products, Plaintiffs were injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III: GENERAL NEGLIGENCE
(Against All Defendants)

420. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

421. Defendants, directly or indirectly, designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products that were used by Plaintiffs.

422. At all relevant times, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products, including the duty to take all reasonable steps

necessary to design, manufacture, test, market, label, package, handle, distribute, store, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

423. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of ranitidine and, specifically, the carcinogenic properties of NDMA when ranitidine-containing products are ingested and/or the elevated levels of NDMA that occurs when ranitidine-containing products are transported and stored.

424. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that their ranitidine-containing products were highly unstable and that ranitidine-containing products were not safe for human consumption for as long as the labeling suggested.

425. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that their ranitidine-containing products were likely to break down in the absence of sufficient packaging which would have protected the pills from heat and/or light exposure.

426. Accordingly, at all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that use of ranitidine-containing products could cause or be associated with Plaintiffs' injuries, and thus create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiffs.

427. All Defendants are well aware of the need to maintain sensitive pharmaceutical drugs under proper shipping and storage conditions, and that maintaining the highest safety techniques is best for the consumer. Pharmaceutical transportation companies are well aware of the importance of precise temperature control down to the degree, and advertise on their ability to provide precise, quality service. More precise, colder transportation is more expensive than less precise, warmer transportation.

428. Upon information and belief, all Defendants systematically exposed ranitidine to excessive levels of heat and humidity that violated the instructions on the products' labels. All Defendants failed to implement rigorous policies to ensure substantial compliance with the heat and humidity requirements on product labels. This failure led to widespread noncompliance.

429. Manufacturer Defendants transport finished drug product from their facilities to distributor warehouses, as well as storing finished drug products in their facilities.

430. Some Manufacturer Defendants also purchase Active Pharmaceutical Ingredients (API), which they store at their facilities. Their agreements with API manufacturers govern how API is transported to them. The storage and transportation conditions of API are not dictated by the label for finished ranitidine-containing products and may differ. For example, any Manufacturer Defendant could have required the API shipped to them to be kept in cold storage.

431. Manufacturer Defendants systematically caused Ranitidine-Containing Products to be exposed to excessive levels of heat and/or humidity during manufacture, storage, shipping and handling that violated the instructions on the finished products' labels and caused ranitidine to degrade more quickly thereby increasing the levels of NDMA in the product.

432. Manufacturer Defendants failed to ensure that their finished Ranitidine-Containing Products were stored and transported safely and were not exposed to excessive heat and humidity.

433. Manufacturer Defendants failed to ensure that API they stored, transported, or over which they could control storage or transportation, were not exposed to excessive heat and humidity. Manufacturer Defendants failed to implement rigorous policies to ensure substantial compliance with the heat and/or humidity requirements on product labels. This failure led to widespread noncompliance.

434. Manufacturer Defendants failed to properly monitor temperature and/or humidity levels during storage and transport. Transporting ranitidine in ordinary trucks, ships, and planes without temperature and humidity control was common among all Manufacturer Defendants. This included transportation in hot locations such as India, Spain, and Mexico, where most ranitidine is manufactured. Storing ranitidine in facilities without careful temperature or humidity control was also common.

435. Manufacturer Defendants failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were stored and transported safely and were not exposed to excessive heat and humidity.

436. Manufacturer Defendants knew or should have known of the need for storing and transporting finished Ranitidine-Containing Products within the labeled temperature range and at low humidity, and for storing and transporting ranitidine API at a reasonable, low temperature that would prevent degradation, and at low humidity.

437. Manufacturer Defendants ignored this risk. They did not ensure ranitidine API and Ranitidine-Containing Products were stored at low humidity or within the temperature range on the label. Instead, ranitidine API and Ranitidine-Containing Products were subjected to excessive humidity and/or heat during transportation and shipping which caused the drug to degrade leading to the formation of excessive levels of NDMA.

438. Ignoring the risks of degradation and NDMA forming was unreasonable and reckless.

439. GSK itself recognized that ranitidine was unstable and hygrophobic. Subsequent NDA- and ANDA-holders learned of this when each began manufacturing.

440. Ranitidine's inherent instability was reinforced by repeated reports of discoloration.

441. GSK noted discoloration in ranitidine pills time after time. Usually, it concluded that faulty temperature or humidity control was to blame. Sometimes, it could not definitively identify a root cause.

442. Pfizer, BI, and Patheon also noticed discoloration and odors that should not have been present. They too concluded at various times that the reason was exposure to heat or humidity, and at various times could not discern a root cause.

443. Each Generic Manufacturer noticed the same problems of discoloration and odors. Each knew that temperature and humidity degrades pharmaceuticals in general, and that ranitidine in particular was unstable in the presence of humidity and heat.

444. Rather than require cold-storage, blister packs, an effective desiccant, reduce expiration dates, and other effective methods, each manufacturer either tolerated or hid the problem.

445. Many manufacturers—including GSK—changed the color of their ranitidine from white to pink, yellow, or another color that did not show discoloration as easily. This simply made discoloration less noticeable, but did not reduce the amount of degradation.

446. Other manufacturers simply told their quality control to ignore most discoloration on the ground that it was not a quality or safety problem. But it was a safety problem, because one of the degradants from ranitidine is NDMA, a potent carcinogen.

447. Defendants knew or, in the exercise of reasonable care, should have known that users and consumers of ranitidine-containing products were unaware of the risks and the magnitude of the risks associated with use of ranitidine-containing products.

448. Defendants knew or should have known that it was foreseeable that consumers such as Plaintiffs would suffer injuries as a result of Defendants' failure to exercise ordinary care in the

design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products.

449. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

450. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

451. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiffs, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to mitigate these dangers or inform the unsuspecting public, including Plaintiffs, about those dangers.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV: NEGLIGENT MISREPRESENTATION
(Against All Defendants)

452. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

453. This Count alleges a claim by Plaintiffs for misrepresentations by Defendants about their own product that Plaintiffs ingested. In addition, this Count alleges claims against the Defendants for misrepresentations Plaintiffs relied upon in ingesting generic ranitidine. Plaintiffs do not allege this Count against Defendants who made misrepresentations only after Plaintiffs stopped consuming ranitidine, but does allege this Count against Defendants who made misrepresentations before Plaintiffs consumed ranitidine, to the extent that the misrepresentations harmed Plaintiffs. Moreover, Plaintiffs do not allege this Count against Patheon, and allege it against GSK only based on its negligent misrepresentations that it made as the NDA-holder.

454. Manufacturer Defendants were negligent, reckless, and careless and owed a duty to Plaintiffs to make accurate and truthful representations regarding ranitidine-containing products, and Manufacturer Defendants breached their duty, thereby causing Plaintiffs to suffer harm.

455. Manufacturer Defendants represented to Plaintiffs via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations described herein that:

a. ranitidine-containing products were both safe and effective for the lifetime of the product, when in fact, the drug contains unsafe levels of NDMA far in excess of the 96ng limit that increases at various points during the shipping, handling, storage, and consumption phases and as the product ages;

b. consumption of ranitidine-containing products would not result in excessive amounts of NDMA being formed in their bodies; and

c. the levels of NDMA in ranitidine-containing products have no practical clinical significance; and

d. ranitidine-containing products were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose.

456. These representations were false. Because of the unsafe levels of NDMA in ranitidine-containing products, the drug presented an unacceptable risk of causing cancer. Ranitidine-containing products are so unsafe that the FDA was compelled to order the immediate withdrawal of all ranitidine-containing products on April 1, 2020.

457. Manufacturer Defendants knew or should have known these representations were false and negligently made them without regard for their truth.

458. Manufacturer Defendants had a duty to accurately provide this information to Plaintiffs. In concealing this information from Plaintiffs, Manufacturer Defendants breached their duty. Manufacturer Defendants also gained financially from, and as a result of their breach.

459. Manufacturer Defendants intended for Plaintiffs to rely on these representations.

460. Each of these misrepresentations were material at the time they were made. In particular, each of the misrepresentations concerned material facts that were essential to the analysis undertaken by Plaintiffs as to whether to purchase or consume ranitidine-containing products.

461. Plaintiffs reasonably relied on these representations and was harmed as described herein. Plaintiffs' reliance on Manufacturer Defendants' representations was a substantial factor in causing Plaintiffs' harms. Had Manufacturer Defendants told Plaintiffs the truth about the safety and composition of ranitidine-containing products, Plaintiffs would not have consumed or purchased them.

462. Manufacturer Defendants' acts and omissions as described herein were committed in reckless disregard of Plaintiffs' rights, interests, and well-being to enrich Defendants.

463. The Brand Name Manufacturers made representations in advertising, in the Physician's Desk Reference, on their New Drug Application (which was submitted to the FDA, but broadly available to generic manufacturers and doctors), and on their products' label that was equally applicable to generic ranitidine.

464. When the New Drug Application for Zantac changed hands (from GSK to Pfizer, then to Boehringer Ingelheim, and finally to Sanofi), the new holder was required to start with the same label, and the former New Drug Application holder could foresee that the subsequent holder would retain the same misrepresentations on the label, in advertising, and in other locations. In fact, it was even more likely that the subsequent holder would keep the warnings as-is, since it would rely on the expertise of the Brand Name Manufacturer that transferred the New Drug Application to it.

465. If the former New Drug Application holder for Zantac had cured its misrepresentations by warning about cancer before transferring the Application, that warning could not have been removed by later Brand Name Manufacturers without FDA approval. For example, if GSK had added a cancer warning to branded Zantac, that warning would have remained on the label throughout the time Pfizer, Boehringer Ingelheim, and Sanofi sold the product unless the FDA had authorized its removal (which it never would have done, given the risks). Similarly, if any Defendant had withdrawn Zantac, a later Brand Name Manufacturer could not have sold it without FDA approval.

466. Generic manufacturers, as required by law, copied the misrepresentations Brand Name Manufacturers made onto their own labels.

467. In using or recommending the use of generic ranitidine, consumers and doctors relied on, and were expected to rely on, the misrepresentations the Brand Name Manufacturers made in advertising, in the Physician's Desk Reference, on their New Drug Application, and on branded Zantac's label. As a result, Plaintiffs were harmed by the Brand Name Manufacturers' misrepresentations when they consumed generic ranitidine without knowing its risks.

468. Plaintiffs were harmed not only by the misrepresentations made by the holder of the New Drug Application when each purchased generic ranitidine, but also the misrepresentations made by the prior New Drug Application holders, because each of those entities could have cured the misrepresentation by disclosing the cancer risk. For example, if GSK had disclosed a cancer risk before Plaintiffs consumed ranitidine, that disclosure would have reached Plaintiffs, because it would have been a required disclosure on the label, in marketing, in the Physician's Desk References, and in other materials from the point of disclosure until the FDA authorized the removal of the warning (which it would not have done).

469. As a direct and proximate result of the Manufacturer Defendants' negligent misrepresentations concerning their ranitidine-containing products, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT V: NEGLIGENCE – FAILURE TO WARN
(Against All Defendants)

470. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

471. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

472. NDMA is a potent carcinogen in humans. Higher exposure to NDMA over longer time periods leads to even higher risks of cancer.

473. To mitigate degradation of ranitidine into NDMA in the stomach, over time, and in the presence of heat or humidity, consumers could be warned:

a. To consume ranitidine shortly after manufacturing and to store it in a cool, dry place (e.g., not in a bathroom). No ranitidine containing product contained this warning.

b. To consume ranitidine for only short periods of time. No ranitidine-containing product warned that cancer could result from long-term ingestion of ranitidine.

c. Not to take ranitidine with or after meals or in combination with a high-nitrite diet. No ranitidine-containing product contained this warning.

d. To take ranitidine with Vitamin E or Vitamin C to inhibit nitrosation and the formation of NDMA in the stomach. No ranitidine-containing product contained this warning.

474. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers should have been warned to consume ranitidine shortly after manufacturing. No ranitidine-containing product contained this warning.

475. In fact, ranitidine-containing products had expiration dating periods of one or two years allowing accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

476. In setting expiration and/or retest dates for their ranitidine-containing drugs, Defendants were required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. *See* 21 C.F.R. § 211.137.

477. A manufacturer has a duty of reasonable care to provide an adequate warning about known risks. The risk posed from NDMA in ranitidine was known and/or knowable by Defendants. Defendants' duty of care owed to consumers and the general public included the duty to provide accurate, true, and correct information concerning the risks of using ranitidine containing products and appropriate, complete, and accurate warnings concerning the potential adverse effects of ranitidine-containing products and, in particular, its ability to transform into the carcinogenic compound NDMA. Defendants had a continuing duty to provide appropriate and accurate warnings and precautions.

478. Defendants, as manufacturers and sellers of pharmaceutical medication, are held to the knowledge of an expert in the field.

479. At all relevant times, Defendants negligently designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings concerning the dangerous characteristics of ranitidine and NDMA.

480. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of ranitidine-containing products and, specifically, the carcinogenic properties of NDMA when ranitidine is ingested. Defendants knew or should have known about each of these risks in time to warn consumers.

481. Even though Defendants knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to ranitidine-containing products. The dangerous propensities of ranitidine-containing products and the carcinogenic characteristics of NDMA, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they manufactured, marketed, distributed, supplied, or sold the products, but were not known to end users and consumers, including Plaintiffs.

482. Defendants negligently failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in ranitidine-containing products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

483. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have

known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

484. At various points in time, Defendants possessed new information or new analyses of existing information that empowered them unilaterally to change the warnings and precautions section of their ranitidine-containing products' label.

485. At all relevant times, Defendants negligently failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their products and to those who would foreseeably use or be harmed by ranitidine.

486. Each individual Defendant breached this duty for the ranitidine-containing products it manufactured, marketed, and sold. The warnings included on each ranitidine- containing product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored or transported under humid conditions, when stored or transported under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture. Plaintiffs and/or their doctors would have read and heeded these warnings. As a result, Plaintiffs would not have ingested ranitidine and would not have developed cancer or otherwise been harmed by exposure to NDMA in these products.

487. Despite this ability, Defendants failed to warn of the risks of NDMA in the warnings and precautions section of their ranitidine-containing products' label.

488. Plaintiffs were exposed to Defendants' ranitidine-containing products without knowledge of their dangerous characteristics. Plaintiffs could not have reasonably discovered the risks associated with ranitidine-containing products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and Plaintiffs' physicians relied upon the skill, superior knowledge, and judgment

of Defendants to know about and disclose serious health risks associated with using Defendants' products.

489. At all relevant times, Plaintiffs used and/or were exposed to Defendants' ranitidine-containing products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

490. Defendants knew or should have known that the minimal warnings disseminated with their ranitidine-containing products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of ranitidine-containing products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

491. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their ranitidine-containing products on the warnings and precautions section of their products' labels, Plaintiffs could have avoided the risk of developing cancer and could have obtained or used alternative medication. However, as a result

of Defendants' concealment of the dangers posed by their ranitidine-containing products, Plaintiffs were not alerted, and so could not avert Plaintiffs' injuries.

492. Defendants' conduct, as described above, was reckless.

493. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with ranitidine-containing products and suppressed this knowledge from the public. Defendants made conscious decisions not to warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

494. Defendants' lack of adequate warnings and instructions in the warnings and precautions section of their ranitidine-containing products' labels were a substantial factor in causing Plaintiffs' injuries.

495. As a direct and proximate result of Defendants' failure to provide an adequate warning of the risks of ranitidine-containing products, Plaintiffs suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to, past and future medical expenses, lost income, and other damages.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VI: NEGLIGENT STORAGE AND TRANSPORTATION (Against All Defendants)

496. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

497. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

498. Defendants were aware of the need to maintain sensitive pharmaceutical drugs under proper shipping and storage conditions, and that maintaining the highest safety techniques is best for the consumer. Pharmaceutical companies are well aware of the importance of precise temperature control down to the degree, and advertise on their ability to provide precise, quality service. More precise, colder transportation is, of course, more expensive than less precise, warmer transportation.

499. Testing of the quantity of NDMA in ranitidine performed to date has shown substantial variation among different batches. Some ranitidine has significantly more NDMA when tested.

500. NDMA forms due to chemical reactions in the human body, and also from degradation before consumption (principally heat, humidity, or time). Testing is performed before consumption and the age of the ranitidine is documented, so neither time nor degradation in the body should produce substantial variation. The best inference must be that substantial variation in heat and humidity is causing differing amounts of NDMA to form.

501. Different ranitidine-containing products listed slightly different storage and transportation requirements.

502. Defendants systematically exposed ranitidine to excessive levels of heat and humidity that violated the instructions on the products' labels.

503. Defendants failed to implement rigorous policies to ensure substantial compliance with the heat and humidity requirements on product labels. This failure led to widespread noncompliance.

504. For example, Defendants shipped ranitidine-containing products through the mail. This method of transportation—whether through the United States Postal Service or large common

carriers such as FedEx and UPS—does not guarantee controlled temperature or humidity. Because of Defendants' choice to use or allow this method of transportation, ranitidine-containing products shipped through the mail were systematically subject to excessive heat or humidity on days when the weather was hot or humid.

505. Defendants, directly or indirectly, transported, stored, handled, and/or sold ranitidine-containing products that were used by Plaintiffs.

506. At all relevant times, Defendants, had a duty to exercise reasonable care in the storage and transportation of ranitidine-containing products to ensure the products were not unreasonably dangerous to consumers and users.

507. Defendants breached this duty by failing to implement or enforce policies to ensure ranitidine-containing products remained free from excessive heat and humidity, as required both by the duty of reasonable care and the label.

508. At all relevant times, Defendants knew or should have known of the need for storing and transporting ranitidine-containing products within the labeled temperature range and at low humidity. Yet, Defendants ignored this risk. They did not ensure ranitidine-containing products were stored at low humidity or within the temperature range on the label. Instead, some ranitidine was subjected to excessive humidity and heat during storage, transportation, and shipping which caused the drug to degrade leading to the formation of excessive levels of NDMA.

509. Ignoring the risks of NDMA forming was unreasonable and reckless.

510. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to ranitidine-containing products.

511. Defendants' negligence was a substantial factor in causing Plaintiffs' injuries.

512. As a direct and proximate result of Defendants' failure to store and transport ranitidine-containing products properly, Plaintiffs have suffered injuries, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

513. As a direct and proximate result of these systematic failures, excessive levels of NDMA formed in the ranitidine-containing products the Defendants handled, stored and sold. These high levels of NDMA caused Plaintiffs' injuries.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VII: APPARENT MANUFACTURER LIABILITY (Against Retailer Defendants)

514. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

515. At all relevant times, each Retailer Defendant sold ranitidine under their respective store brand and had control over the contract manufacturer's design, labeling, packaging, manufacture, testing, and distribution.

516. At all relevant times, each Retailer Defendant affixed their own brand labeling on their ranitidine products, and consumers—like Plaintiffs—believed the Retailer Defendants' store brand acetaminophen was manufactured by (or specifically for) the Retailer Defendants.

517. For example, a consumer would reasonably assume that Equate was manufactured by Walmart. And a consumer would reasonably assume that Wal-Zan was manufactured by Walgreens. At minimum, consumers would reasonably assume that these products were made specifically for the Retailer Defendants, as its branding suggests.

518. Each Retailer Defendant was therefore an "apparent manufacturer" of their respective store brand ranitidine.

519. As apparent manufacturers, the Retailer Defendants were liable to the same extent a manufacturer would be for the design, labeling, packaging, manufacture, testing, distribution, and selling of their store brand ranitidine products.

520. The Retailer Defendants' store brand ranitidine had cancer-causing NDMA; said nothing about NDMA or cancer; was stored in a way that allowed the ranitidine to degrade into NDMA; and was not expected to contain NDMA.

521. The Retailer Defendants therefore breached their duty to consumers.

522. The NDMA in Retailer Defendants' ranitidine products was a substantial factor in causing Plaintiffs' injuries.

523. The Retailer Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of their respective store brand ranitidine in order to advance their own financial interests, with wanton and willful disregard for the rights and health of Plaintiffs.

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VIII: LOSS OF CONSORTIUM
(Against All Defendants)

524. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

525. At the time of the losses, injuries, and damages complained of herein, each Plaintiff and Plaintiff Spouse were married and continue to be married.

526. That as a direct and proximate result of the wrongful and negligent acts of Defendants, and each of them, each Plaintiff and Plaintiff Spouse were caused to suffer, and will

continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship.

WHEREFORE, each Plaintiff and Plaintiff Spouse respectfully request this Court to enter judgment in each Plaintiff and Plaintiff Spouse's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IX: WRONGFUL DEATH
(Against All Defendants)

527. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

528. Plaintiffs Decedents' spouses, beneficiaries, and/or lawful representatives of Decedents' Estates bring this claim on behalf of themselves and as the Decedents' lawful beneficiaries.

529. As a direct and proximate result of the negligent and wrongful acts of Defendants and the defective nature of ranitidine-containing products as outlined above, Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses, and death.

530. As a direct and proximate cause of the conduct of Defendants, Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths.

531. Plaintiffs or the Estates of the Decedents are entitled to damages for the harms inflicted upon the decedent.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in their favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT X: SURVIVAL ACTIONS
(Against All Defendants)

532. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

533. As a direct and proximate result of the conduct of Defendants, Decedents, prior to their deaths, were obligated to spend various sums of money to treat their injuries, which debts have been assumed by their estates. As a direct and proximate cause of the aforesaid, Decedents were caused paid and suffering, mental anguish and impairment of the enjoyment of life, until the date of their deaths, and Decedents suffered a loss of earnings and earning capacity. Plaintiffs' spouse, as Administrators of the Estates of Decedents, beneficiaries, and/or lawful representatives bring this claim on behalf of the estates for damages under any and all applicable statute or common law.

534. As a direct and proximate cause of the conduct of Defendants, Decedents and their spouses, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression, and other symptoms of psychological stress and disorder.

535. As a direct and proximate result of the conduct of Defendants and including the observances of the suffering of Decedents, until the date of their deaths, Plaintiffs suffered permanent ongoing psychological damage.

536. As a direct and proximate result of the aforesaid and including the observance of the suffering and physical deterioration of Decedents until the date of their deaths, Plaintiffs have and will continue to suffer permanent and ongoing psychological damages which may require

future psychological and medical treatment. Plaintiffs' spouse, as Administrators of the Estates of the Decedents, beneficiaries, and/or lawful representatives bring the claims on behalf of the Estates for damages any and all applicable statutes or common law and in their own right.

537. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

538. As a result of Defendants' conduct, Plaintiffs suffered the injuries and damages specified herein.

539. The Estates of the Decedents are entitled to damages for the harms inflicted upon the decedent.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in their favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XI: ILLINOIS CONSUMER FRAUD ACT
(Against All Defendants)

540. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

541. Defendants intentionally and/or with reckless disregard for the truth misrepresented to Plaintiffs material facts regarding the safety and effectiveness of ranitidine.

542. Defendants knew or recklessly disregarded the fact that these representations were false, yet made the deceitful representations to Plaintiffs.

543. Defendants actively concealed and intentionally omitted material facts about the defects and dangers of ranitidine for the purpose that Plaintiffs and the consuming public would rely on such information, or the absence of information, in selecting ranitidine as a treatment.

544. The Defendants' intentional material misrepresentations and omissions as described fully in this Complaint constitute deceptive acts or practices under the Illinois Consumer Fraud Act.

545. The Defendants engaged in these deceptive acts or practices with the intent that Plaintiffs would rely on the deceptions.

546. Defendants made the misrepresentations and omissions of material facts alleged herein with the intent to induce consumers, like Plaintiffs, to purchase their ranitidine products.

547. The deceptions committed by Defendants as described herein occurred in the course of conduct involving trade and commerce, i.e., Defendants made such material misrepresentations and omissions as an inducement for Plaintiffs and other consumers to purchase their products in the stream of commerce, from which Defendants collectively earned billions of dollars from the sales of ranitidine products.

548. As a result of these false and deceitful representations and omissions made by Defendants, which Defendants knew to be untrue or for which Defendants recklessly disregarded the truth, Plaintiffs in fact relied on such misrepresentations and omissions by purchasing and ingesting Defendants' ranitidine products, thus causing the significant injuries and harm described herein.

549. As a direct and proximate result of the foregoing misrepresentations omissions, and deceitful intentions, Plaintiffs sustained serious injuries of a personal and pecuniary nature. Plaintiffs suffered serious injuries, including cancer and permanent disability and disfigurement.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in their favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XII: COMMON LAW FRAUD
(Against All Defendants)

550. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

551. Defendants intentionally and/or with reckless disregard for the truth misrepresented to Plaintiffs material facts regarding the safety and effectiveness of ranitidine.

552. Defendants knew or recklessly disregarded the fact that these representations were false, yet made the deceitful representations to Plaintiffs.

553. Defendants actively concealed and intentionally omitted material facts about the defects and dangers of ranitidine for the purpose that Plaintiffs and the consuming public would rely on such information, or the absence of information, in selecting ranitidine as a treatment.

554. The maker's knowledge of the falsity of the representation fundamentally supplies the element of "fraudulent utterance" required to make a misrepresentation actionable.

555. Defendants made the misrepresentations and omissions of material facts alleged herein with the intent to induce consumers, like Plaintiffs, to take their ranitidine products.

556. As a result of these false and deceitful representations and omissions made by Defendants, which Defendants knew to be untrue or for which Defendants recklessly disregarded the truth, Plaintiffs in fact relied on such misrepresentations and omissions by purchasing and ingesting Defendants' ranitidine products, thus causing the significant injuries and harm described herein.

557. As a direct and proximate result of the foregoing misrepresentations omissions, and deceitful intentions, Plaintiffs sustained serious injuries of a personal and pecuniary nature. Plaintiffs suffered serious injuries, including cancer and permanent disability and disfigurement. As a direct and proximate result of the foregoing misrepresentations, omissions, and deceitful intentions, Plaintiffs require and/or will require more healthcare and services and did incur

medical, health, incidental, and related expenses. Plaintiffs will also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in their favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XIII: BREACH OF EXPRESS WARRANTIES
(Against All Defendants)

558. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

559. The brand name Zantac ranitidine-containing products complained of were designed, manufactured, advertised, marketed, distributed, and/or sold by the Defendants, which Plaintiffs regularly used and ingested.

560. The generic ranitidine-containing products, including Wal-Zan, were advertised, marketed, distributed, and/or sold by the Walgreens Defendants, which Plaintiffs regularly used and ingested.

561. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting ranitidine-containing products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, thereby placing ranitidine-containing products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

562. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of ranitidine-containing products, including ranitidine syrup, including a duty to:

a. ensure that their products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects;

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to ranitidine, when making representations to the FDA, consumers and the general public, including Plaintiffs; and

d. set proper expiration dates and storage temperatures and disclose the adverse consequences should ranitidine not be stored properly.

563. As alleged throughout this pleading, the ability of Defendants to properly disclose those risks associated with its drugs are not limited to representations made on the labeling.

564. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that ranitidine-containing products were safe to human health and the environment, effective, fit, and proper for their intended use. Defendants advertised, labeled, marketed, and promoted its products, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that its ranitidine-containing products would conform to the representations.

565. These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to ranitidine. Defendants knew and/or should have known that the risks expressly included in the warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that its ranitidine tablets were safe and effective, that it was safe and effective for use by individuals such as Plaintiffs, and/or that it was safe and effective as consumer medication.

566. The representations about ranitidine tablets, as set forth herein, contained, or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

567. Plaintiffs purchased ranitidine products directly at Walgreens retail locations throughout Illinois and the United States.

568. Plaintiffs are third-party beneficiaries of the various contracts that Defendants entered into for the distribution and retail sale of their Zantac products.

569. Defendants placed ranitidine tablets into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the ingestion of improperly stored ranitidine.

570. Defendants breached these warranties because, among other things, ranitidine products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways:

a. Defendants represented through their labeling, advertising, and marketing materials that its products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with improper storage and handling of use ranitidine; and

b. Defendants represented that its products were safe for use and intentionally concealed information that demonstrated that ranitidine, by transforming into NDMA when improperly stored or handled, had carcinogenic properties, and that its products, therefore, were not safer than alternatives available on the market.

571. Plaintiffs detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of ranitidine in deciding to purchase the product. Plaintiffs reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of its products if not stored, shipped and handled properly. Plaintiffs would not have purchased brand OTC ranitidine tablets had Defendants properly disclosed the risks associated with the products, either through advertising, labeling, or any other form of disclosure.

572. Defendants had sole access to material facts concerning the nature of the risks associated with their products, as expressly stated within their warnings and labels, and knew that consumers and users such as Plaintiffs could not have reasonably discovered that the risks expressly included in its warnings and labels were inadequate and inaccurate.

573. Plaintiffs had no knowledge of, and could not reasonably have discovered, the falsity or incompleteness of Defendants' statements and representations concerning ranitidine.

574. Plaintiffs used and/or were exposed to ranitidine as manufactured, tested, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

575. Had the labels, advertisements, or promotional material for its products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that the products were safe for their intended use, Plaintiffs could have avoided the injuries complained of herein.

576. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs have sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

577. As a proximate result of Defendants' breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiffs suffered great mental anguish and other personal injury and damages.

578. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiffs sustained a loss of income and/or loss of earning capacity.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in their favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XIV: BREACH OF IMPLIED WARRANTIES (Against All Defendants)

579. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

580. This Count alleges a claim by each Plaintiff for ranitidine he or she consumed and that each Defendant manufactured or sold.

581. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products, which were and are defective and unreasonably dangerous to consumers, including Plaintiffs, thereby placing ranitidine-containing products into the stream of commerce.

582. Before the time Plaintiffs used ranitidine-containing products, Defendants impliedly warranted to their consumers, including Plaintiffs, that ranitidine-containing products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

583. Ranitidine was not merchantable, not safe, and not fit for its use as a consumer medication because it degraded into NDMA, a potent carcinogen. By selling ranitidine despite these flaws, Defendants breached their implied warranties.

584. Plaintiffs purchased ranitidine products directly at Walgreens retail locations throughout Illinois and the United States. Plaintiffs are third-party beneficiaries of the various contracts that Defendants entered into for the distribution and retail sale of their Zantac products.

585. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiffs, would use ranitidine-containing products as marketed by Defendants, which is to say that Plaintiffs were a foreseeable user of ranitidine-containing products.

586. Defendants intended that ranitidine-containing products be used in the manner in which Plaintiffs, in fact, used them and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though ranitidine-containing products were not safe because they degraded into NDMA.

587. In reliance upon Defendants' implied warranty, Plaintiffs used ranitidine-containing products as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

588. Plaintiffs could not have reasonably discovered or known of the risks of serious injury associated with ranitidine-containing products.

589. The harm caused by Defendants' ranitidine-containing products far outweighed their benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

590. Defendants' breach of these implied warranties was a substantial factor is causing Plaintiffs' harm.

591. As a direct and proximate result of Defendants' breach of implied warranties, as alleged herein, Plaintiffs sustained a loss an economic loss and other injuries.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in their favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XV: UNJUST ENRICHMENT
(Against Manufacturer Defendants)

592. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

593. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released ranitidine-containing products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that consumed it, including Plaintiffs.

594. Defendants knew that ranitidine-containing products posed a grave risk of harm but failed to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the carcinogenic characteristics of NDMA were well known to Defendants.

595. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that omitted disclosure that the products presented an unreasonable risk of substantial bodily injury resulting from their use.

596. Defendants requested and received a measurable benefit at the expense of Plaintiffs in the form of payment for their ranitidine-containing products.

597. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiffs conferred onto Defendants at Plaintiffs' detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiffs.

598. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

599. Defendants wrongfully obfuscated the harm caused by their ranitidine-containing products. Thus, Plaintiffs, who mistakenly enriched Defendants by relying on Defendants' misrepresentations of product safety, could not and did not know the effect that using ranitidine-containing products would have on their health.

600. Plaintiffs are entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return them to the position they occupied prior to dealing with Defendants. Due to their wrongful conduct and the FDA action recalling ranitidine-containing products in the form of a market withdrawal, Defendants are reasonably notified that Plaintiffs would expect compensation from Defendants' unjust enrichment stemming from their wrongful actions.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XVI: CIVIL CONSPIRACY
(Against Manufacturer Defendants)

601. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

602. Brand Manufacturer Defendants and/or their predecessors-in-interest knowingly agreed, contrived, combined, confederated, and conspired among themselves to cause Plaintiffs injuries, disease, and/or illnesses by exposing Plaintiffs to harmful and dangerous Zantac.

603. Brand Manufacturer Defendants further knowingly agreed, contrived, confederated, and conspired to withhold from consumers such as Plaintiffs scientific data,

adequate labeling, and proper warnings regarding the risk of cancer associated with their NDMA-contaminated Zantac products.

604. Defendants GSK and Pfizer entered into an agreement in 1993 to develop OTC Zantac, which resulted the formulation of the drug, and the withholding of known risks of NDMA contamination, submitted to the FDA for approval in NDA 20-520.

605. All Brand Manufacturer Defendants agreed to withhold from the public known information about NDMA contamination of their respective OTC Zantac products and the resultant increased risk of cancer in their packaging, branding, labeling, advertising, promotional, and marketing activities.

606. The agreements among the Brand Manufacturer Defendants were in contravention of federal and state laws regarding the misbranding of drugs, sale of defective products, and post-approval reporting, including:

a. The Food, Drug, and Cosmetic Act, 21 U.S.C. § 355, et seq., which requires that companies filing an application for a new NDA for approval submit, *inter alia*, "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A)(i);

b. The Food, Drug, and Cosmetic Act, 21 U.S.C. § 352 which declares a drug to be misbranded if the label "is false or misleading in any particular," 21 U.S.C. §352(a)(1), and further requires the label to include "(1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." *Id.* at § 352(f). Furthermore, a drug can be misbranded if it is deteriorative and the label fails to contain a statement of such precautions. *Id.* at 352(h).

c. FDA Regulations, 21 C.F.R. Part 314, which require, *inter alia*, the following post-marketing reports:

1. A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product, along with a report of the steps the NDA applicant intends to take as a result of this information, including adding a warning to the label. 21 C.F.R. § 314.81(b)(2)(i).

2. A report of "experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the drug (such as the drug's behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effects of microorganisms on the drug). These reports are only required for new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug product." 21 C.F.R. § 314.81(b)(2)(iv).

3. Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product. 21 C.F.R. § 314.81(b)(2)(v).

4. Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a monitored series of patients) conducted by or otherwise obtained by the applicant. 21 C.F.R. § 314.81(b)(2)(vi); and

d. Parallel state laws that prohibit the dissemination of misbranded drugs.

611. In furtherance of these agreements, the Manufacturer Defendants committed the following overt acts:

a. Defendant GSK withheld the scientific literature of which it was aware related to the risk of developing cancer as a result of taking NDMA contaminated ranitidine, and further issued labels without any warnings related to the presence of NDMA and the resultant increased risk of developing cancer in the labeling of OTC Zantac during the times they developed, packaged, branded, labeled, advertised, promoted, and marketed their Zantac products, including OTC Zantac;

b. Defendant Pfizer withheld the scientific literature of which it was aware related to the risk of developing cancer as a result of taking NDMA contaminated ranitidine, and further issued labels without any warnings related to the presence of NDMA and the resultant increased risk of developing cancer in the labeling of OTC Zantac during the times they developed, packaged, branded, labeled, advertised, promoted, and marketed their Zantac products, including OTC Zantac;

c. Defendant BI withheld the scientific literature of which it was aware related to the risk of developing cancer as a result of taking NDMA contaminated ranitidine, and further issued labels without any warnings related to the presence of NDMA and the resultant increased risk of developing cancer in the labeling of OTC Zantac during the times they developed, packaged, branded, labeled, advertised, promoted, and marketed their Zantac products, including OTC Zantac;

d. Defendant Sanofi withheld the scientific literature of which it was aware related to the risk of developing cancer as a result of taking NDMA contaminated ranitidine, and further issued labels without any warnings related to the presence of NDMA and the resultant increased risk of developing cancer in the labeling of OTC Zantac during the times they developed, packaged, branded, labeled, advertised, promoted, and marketed their Zantac products, including OTC Zantac;

612. As a direct and proximate result of the acts done under this conspiracy by the Brand Manufacturer Defendants, Plaintiffs suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money, aggravation of a previously existing condition, and death.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XVII: STRICT PRODUCTS LIABILITY – PRE-APPROVAL DESIGN DEFECT (Against GSK and Pfizer)

613. Plaintiffs incorporate the preceding paragraphs as if fully stated herein.

614. GlaxoSmithKline was the inventor of ranitidine and was the developer of prescription Zantac under NDA 18-709. GlaxoSmithKline was also the developer of the various OTC Zantac products approved under NDAs 20-520 and 20-745, and all supplements. Pfizer was the developer of various OTC Zantac products approved under NDA 21-698 and all supplements.

615. NDAs 18-709, 20-520, 20-745, and 21-698, and their respective supplements, were approved as new NDAs under section 505(b) of the FDCA.

616. GlaxoSmithKline and Pfizer, as inventor and developers, knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Decedent would not have realized the potential risks and dangers of OTC Zantac.

617. GlaxoSmithKline and Pfizer owed a duty to all reasonably foreseeable users to design a safe product.

618. GlaxoSmithKline and Pfizer breached their duty by failing to use reasonable care in the design of OTC Zantac because the drug exposed users to unsafe levels of the carcinogen NDMA.

619. GlaxoSmithKline and Pfizer breached their duty by failing to use reasonable care in the design of OTC Zantac by negligently designing the drug with an inherent susceptibility to form NDMA. Alternative designs of the molecule—designs that were approved by the FDA—existed that substantially reduced the degradation of ranitidine into unsafe levels of NDMA.

620. GlaxoSmithKline and Pfizer breached their duty by failing to use reasonable care in the design of OTC Zantac:

a. When placed in the stream of commerce, OTC Zantac was defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;
b. When placed in the stream of commerce, OTC Zantac was unreasonably dangerous in that it was hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, OTC Zantac contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d. GlaxoSmithKline and Pfizer did not sufficiently test, investigate, or study OTC Zantac and, specifically, the ability for OTC Zantac to transform into the carcinogenic compound NDMA within the human body;

e. GlaxoSmithKline and Pfizer did not sufficiently test, investigate, or study OTC Zantac and, specifically, the ability for OTC Zantac to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

f. Exposure to ranitidine-containing drugs such as OTC Zantac presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

g. GlaxoSmithKline and Pfizer knew or should have known at the time of marketing OTC Zantac that exposure to OTC Zantac could result in cancer and other severe illnesses and injuries;

h. GlaxoSmithKline and Pfizer did not conduct adequate post-marketing surveillance of their OTC Zantac; and

i. GlaxoSmithKline and Pfizer possessed a columnar grade I ranitidine drug substance that was chemically identical to the ranitidine used in the products consumed by Decedent, but was significantly less prone to degrade into NDMA. This morphology of ranitidine was available for use in the United States, but GlaxoSmithKline and Pfizer chose to use an inferior design.

621. GlaxoSmithKline and Pfizer could have employed safer alternative designs and formulations. For example, GlaxoSmithKline and Pfizer could have added ascorbic acid (Vitamin C) to each dose of OTC Zantac, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

622. A reasonable company under the same or similar circumstances would have designed a safer product.

623. Decedent was harmed directly and proximately by the GlaxoSmithKline's and Pfizer's failure to use reasonable care in the design of OTC Zantac. Such harm includes significant exposure to a known carcinogen, NDMA, which can cause or contribute the development of cancers.

624. GlaxoSmithKline's and Pfizer's defective design of OTC Zantac was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the OTC Zantac, including Decedent.

625. The defects in OTC Zantac were substantial factors in causing Decedent's injuries.

626. As a direct and proximate result of the GlaxoSmithKline's and Pfizer's defective design of the OTC Zantac, Decedent has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages, including her death.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' favor for compensatory damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

627. Pursuant to 735 ILCS 5/2-1105, Plaintiffs hereby demand a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the Court to enter judgment in Plaintiffs' favor and against Defendants for:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. pre-judgment and post-judgment interest;

c. reasonable attorneys' fees as provided by law;

d. costs and expenses of these actions;

e. statutory damages, treble damages and other relief permitted by the laws of the states that will govern these actions; and

f. any other relief the Court may deem just and proper.

Dated: March 9, 2023

Respectfully submitted,
__/s/ *Ashley Keller*_____
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On behalf of all Plaintiffs' Counsel

CERTIFICATE OF SERVICE

Under penalties of perjury pursuant to Section 735 ILCS 5/1-109 of the Code of Civil Procedure, the undersigned certifies that this **Master Complaint** was electronically filed with the Clerk of the Circuit Court using the Odyssey E-File system on March 9, 2023, and the said document is being served on all counsel of record registered to receive service via the Odyssey E-File system and via email.